EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

Jane Doe
Case No. 2:12-cv-00000

ORAL DEPOSITION OF STANTON SHOEMAKER, M.D.
APRIL 5, 2016

ORAL DEPOSITION OF STANTON SHOEMAKER, M.D., produced as a witness at the instance of the Plaintiffs and duly sworn, was taken in the above styled and numbered cause on Tuesday, April 5, 2016, from 9:11 a.m. to 2:14 p.m., before RENE WHITE MOAREFI, CSR, CRR, RPR in and for the State of Texas, reported by computerized stenotype machine, at the offices of Sico, Hoelscher, Harris & Braugh, 802 N. Carancahua, Suite 900, Corpus Christi, Texas, pursuant to the Federal Rules of Civil Procedure and any provisions stated on the record herein.

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EXHIBITS

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STANTON SHOEMAKER, M.D.,
having been duly sworn, testified as follows:

EXAMINATION

BY MR. MONSOUR:

Q. Would you please state your name.
A. Edward Stanton Shoemaker.
Q. Do you go by Stan Shoemaker?
A. Yes.
Q. Okay. What do you do for a living, sir?
A. I'm a physician.
Q. Okay. And what kind?
A. I practice OB/GYN.
Q. Okay. Do you deliver babies?
A. Yes.
Q. Still do?
A. Unfortunately.
Q. Okay. Why do you say unfortunately?
A. Well, normally by my age everybody's just doing gynecology, but that's changed a lot. And so -- actually, I quit doing OB about -- for about a year and my practice aged about 20 years in about two months.

So I decided, well, you know, I'd like to have a little more diversity in terms of demographics and, so I went back to doing some -- so I do OB light.

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MS. BECK: Can you have Dr. Shoemaker speak up? I can't hear him.

MR. MONSOUR: Oh, they're saying they can't hear you. I'm going to push this a little closer to Dr. Shoemaker.

MS. DEMING: In fact, he delivered twins this morning.

Q. (BY MR. MONSOUR) Delivered twins this morning? Okay.

A. Well, I -- yeah, about 11:00 o'clock last night so . . .

Q. Okay.

A. Yeah.

Q. All right. I was going to say, because I would think doing OB, that's that -- that's got to be one of the happiest parts of medicine, right?

A. It usually is.

Q. Yeah.

A. Yes.

Q. I mean, 95 percent of the time unless there's -- something bad happens, right?

A. Yes.

Q. Let me ask you a little bit about your -- your practice. So you -- in this practice or in this

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litigation, we have gynecologists, we have urologists, we have urogynecologists. Would you classify yourself by your practice as a urogynecologist or gynecologist?

A. I'd say gynecologist.

Q. Okay.

A. Yes.

Q. Now, you have been practicing medicine -- I mean, just give me the run-through of your -- of your education and all that kind of stuff.

A. I'm from -- I grew up in Houston --

Q. Okay.

A. -- and went to college at UCLA out in California and came back in the -- in 1969 and started med school at Galveston. And I was there from 1969 to '73 and then went from Galveston to UT Dallas at Southwestern from '73 to '77 doing a residency in OB/GYN.

Q. Okay.

A. And then moved from there to Corpus in seventy -- the late '77 and have been there ever since.

Q. I looked on your Web site. It said -- and I'll probably get this wrong, but you'll know where I'm going. It said you opened the first OB/GYN practice in South Texas?

A. I opened the first group practice.

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Q. What -- what's the difference there?

A. Well, there were several doctors that actually came together and shared patients instead of having solo practices that just had a call arrangement.

Q. Okay.

A. So we started that in Corpus --

Q. Okay.

A. -- in the late Seventies.

Q. Okay. So there were a lot of OB/GYNs in South Texas. This was just the first time y'all got together as a group?

A. Correct.

Q. Okay. And it looks like -- are you board certified?

A. Yes.

Q. And what are you board certified in?

A. In OB/GYN.

Q. Okay. Okay. So I want to go through a couple of things, if I could.

MR. MONSOUR: Do we have the notice for the deposition?

Q. (BY MR. MONSOUR) So let me hand you, Dr. Shoemaker --

(Exhibit 1 marked.)

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Q. (BY MR. MONSOUR) Here's Exhibit 1. And this is the notice for your deposition.

I take it you at least were able to glance at that before you got here; is that correct?

A. Yes. Well, I've seen it before. I can't remember when.

Q. And it -- if you look kind of on -- starting on page 7, it's got a list of things that you were supposed to bring with you today. Do you see that?

A. Yes.

Q. And did you bring all that --

A. Yes.

Q. -- stuff that's requested?

A. Yes.

MS. DEMING: I think there were some objections filed to some of them, and subject to those objections, we've brought everything responsive that he has.

MR. MONSOUR: Okay. And, Kay, you had mentioned that you're going to be providing us with a thumb drive later today. It's not --

MS. DEMING: I brought them --

MR. MONSOUR: Okay.

MS. DEMING: -- just so that we are abiding

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by the law. We don't want to run afoul a Texas judge, or even Judge Goodwin.

So I brought the thumb drives that were sent to him, okay, and these include the case-specific ones. Later today -- apparently, FedEx does not deliver for early delivery to a hotel here in Corpus Christi. So I should have by lunchtime.

MR. MONSOUR: Okay.

MS. DEMING: If y'all need it, I can go over to the hotel or have it couriered over. The thumb drives that don't have -- that don't -- they'll have a password, they're password protected because they have confidential stuff, but it's the one that they give to the plaintiffs.

MR. MONSOUR: Okay.

MS. DEMING: So it's one that you've used before. And I don't know what it is, but they'll tell you.

MR. MONSOUR: And then the only other question I have is could you tell me which objections, which numbers they had objections lodged to?

MS. DEMING: I did not bring the -- let me see if I've got the notice.

MR. MONSOUR: Or if you've got a copy of your objections, I'll just attach --

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MS. DEMING: I don't have a copy of them, but --

MR. MONSOUR: Ann does. Okay. So let me look.

MS. DEMING: But if -- shoot, I left it at the hotel.

MR. MONSOUR: What I'll do --

MS. DEMING: It's just some that are toward the end that -- one is just very, very overly broad about e-mails and -- because it's really not very specific, and then the tax -- I know the tax ones they've -- they objected to, so we're not providing tax documents. But everything else either he didn't have anything, I believe, or we brought what he has.

MR. MONSOUR: Okay. And I've got -- Ann Gayle just handed me a copy of it. So I'm going to mark it as Exhibit 2 for completeness purposes.

(Exhibit 2 marked.)

MS. DEMING: Okay. This meaning the objection?

MR. MONSOUR: Yeah, the objections --

MS. DEMING: Oh, good, I did --

MR. MONSOUR: -- that's Exhibit 2.

MS. DEMING: No. 12 and No. 16 will stand on

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the objection for sure and then -- yeah, 12 and 16, I believe.

MR. MONSOUR: 12 and 16.

MS. DEMING: And whichever one asks for tax information. Yeah, 11 -- 11, 12, and 16.

And then we've been through the list with him one by one and he -- he has brought what he has, and I'm sure you'll go through it and see what he doesn't have, because there are several of these he just didn't have anything that were responsive.

MR. MONSOUR: All right. Fair enough.

Q. (BY MR. MONSOUR) Now, Dr. Shoemaker, generally speaking, what is your role for Ethicon in this litigation? What do you view it as?

A. They have asked me to serve as an expert regarding pelvic mesh products and as case reviews for some of the mesh litigations that are going on, and so I agreed to review some cases. And then they asked me to do a general report, give my opinion about the product itself, and so I've done that.

MS. BECK: I cannot hear Dr. Shoemaker at all.

THE REPORTER: I'm having trouble, too.

THE WITNESS: You are?

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(Discussion off the record.)

Q. (BY MR. MONSOUR) So one of the things -- have you ever given a deposition before?

A. I have.

Q. Okay. And I'll tell you -- and you probably know this -- they're very conversational. So you and I are going to just talk back and forth. And so sometimes you --

A. Right.

Q. Just remember to keep your voice up so they can hear you on the phone.

A. All right.

Q. All right. So let's go back in. Now, Dr. Shoemaker, what is -- you said you were asked by Ethicon to basically testify with regard to pelvic mesh and I guess to look at some individual plaintiffs, correct?

A. Correct.

Q. And you're providing case-specific reports for those people?

A. Correct.

Q. Did you do actual physical exams on those women?

A. Not all of them.

Q. Okay. Do you know why some you did exams on and

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some you didn't?
A. Not exactly. I think it had to do with whatever the negotiation was between the attorney groups, which ones they wanted me to do.
Q. Okay. But I guess what I'm getting at is you were told in the individual cases you need to do a physical exam on this one and you'll just review medical records on that one?
A. Well -- and some of the medical records I reviewed we haven't done the physical exam yet, but it's in -- it's planned.
Q. Okay. But I guess what I'm saying is, is the determination as to whether or not a physical exam is done on a patient, that decision is made by someone other than you?
A. That's correct.
MS. DEMING: In his cases? You're just talking about in the matters he's working on?
MR. MONSOUR: Yes.
MS. DEMING: Okay.
A. Yes.
Q. (BY MR. MONSOUR) Okay. For your individual -- when you perform an individual exam with regard to a plaintiff in a transvaginal mesh case, how long does a

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physical exam take and what do you typically do?
A. Probably overall an hour or maybe a little bit more, but it involves some history and involves some idea about what their life is like, what it was like before they had their procedure done, what their relationship with their physician who was the -- did the implanting and what -- and what has happened to them after that, et cetera.
So there's a lot of -- a good part of that is sitting down with them and talking to them about their life and what's going on with -- with -- and their complaint. And then -- and so I'd say the majority of that hour and a half or so is probably in history and visiting and then the exam part itself probably takes maybe 15 to 20 minutes.
Q. Okay. Do -- when you're talking to the women that you're examining on behalf of Ethicon, generally speaking, do you find them to be honest?
MS. DEMING: Object to the form.
A. Well, I assume they are. I mean, I don't have any -- I mean, I don't have anything to tell me that they're not.
Q. (BY MR. MONSOUR) Okay.
A. I mean --

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Q. Have you ever -- have you ever thought when you were talking to them and performing exams on them that they were faking?
MS. DEMING: Object to the form.
A. Well, sometimes, you know, like you talk to anybody, you can get an idea -- and they talk to you about one thing and then -- and then they have another explanation later on in the -- in the communication that doesn't fit with what they'd said before and so -- but in term -- in terms of how their body language is, sometimes they can be very -- it's very simple and straightforward and then sometimes it can be somewhat difficult.
But there's not any real -- I don't know, there's not any real way for me to -- because I don't know them very -- you know, I've only met them for a very short period of time, so, you know, I have to make some assumptions --
Q. (BY MR. MONSOUR) Okay.
A. -- about that.
Q. I guess what I'm -- how many of these case-specific exams have you done thus far for Ethicon?
A. I've done three.
Q. You've done three.
And of those three women that you've done

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thus far, did you believe that those women were telling you the truth when they said they're having problems with their transvaginal mesh implants?
A. I believe that they -- I mean, I certainly believe that in their mind that they were -- that that's what they believed.
Q. Okay. Now, let me ask you this: Do you believe that there are women out there that suffer injuries from transvaginal mesh implants?
A. Yes.
Q. And what are some of those injuries that -- that you have seen in your practice?
A. Well --
MS. DEMING: Object to the form.
A. -- I think that the most common complaints with regard to mesh has been erosion or extrusion or -- and -- or exposure, those -- that's another term we use depending on what the circumstances are. So that's one thing that's unique to mesh.
Q. (BY MR. MONSOUR) Okay. Let me interrupt you real quick. Do you use the term "erosion," "extrusion," and "exposure" interchangeably?
A. Not exactly.
Q. Okay. Can you explain the difference for me?

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A. Yeah. I think exposure in my opinion is -- is where the mesh is exposed into the vaginal canal, typically at the incision site, and usually within the first few months of -- of the implant.

Extrusion can sometimes -- you see an exposure of the mesh beyond or somewhere outside maybe the incision line from the implanter.

And erosion is where the mesh actually erodes into what we call a viscus, either into the bladder or into the rectum.

MS. DEMING: Did someone just join the call? Okay.

MR. MONSOUR: This is Doug Monsour talking to the people on the phone. We just heard a blip on the phone. Did somebody join us?

MS. DEMING: Did somebody leave? I guess they're not going to answer if they left.

THE WITNESS: Maybe they couldn't hear me I'm sorry.

MS. DEMING: Who's still on the phone, please?

MS. BOSSIER: Somebody might have hung up. This is Sheila Bossier. I'm still on the phone.

MS. DEMING: Sharon, are you still on the

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phone? Sharon? I guess not.

MR. MONSOUR: She was the one saying she couldn't hear, so she probably just hung up.

Q. (BY MR. MONSOUR) Okay. So is there -- is there any way to determine -- let me start again.

How can issues of erosion, extrusion, or exposure, how can those cause problems for women?

A. Most commonly, they present with some discharge, maybe some bloody discharge, and often -- but oftentimes they have no symptoms. It just is discovered at the time you do an exam. And then sometimes they can -- they can have some discomfort when they have sex.

Q. And why would it cause discomfort when they have sex?

A. Well --

Q. Can you explain that?

A. Well, often it's the husband who is the initial complainer, and so the husband complains to her, "I think I feel something." And, you know, sometimes she may not feel it and sometimes she might feel. It -- it depends.

Q. Okay. What about the issues of -- what about the issue -- what other issues can be caused by transvaginal mesh implants that can cause a woman problems other than erosion, extrusion, and exposure?

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MS. DEMING: Object to the form.

A. Well, in some cases, you have patients who will -- they'll have -- they'll complain of some urinary dysfunction. They may think it's related to the mesh, but there are a lot of other factors that can be a part of that complaint as well. And there may be -- those seem to be the main ones. I would say the -- the issue of exposure and subsequent vaginal discharge, that's -- that's uncomfortable.

Now, if they have an erosion into the bladder or the rectum, then that can cause some difficulty as well, including bleeding. It includes -- and in the bladder, it can include hypermobility of the bladder, overactive bladder and stone formation and chronic infections, urinary tract infections.

Q. (BY MR. MONSOUR) Do you ever perform transvaginal mesh revision surgeries on women that are having problems with their mesh implants?

A. Yes.

Q. And about how many of those have you done over the years?

A. Probably a dozen or so, dozen to maybe -- maybe -- between, I'd say, 12 and 20.

Q. And are those women that had the implant put in

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by you or by other doctors?

A. Other doctors.

Q. Have you ever done a revision surgery on a transvaginal mesh implant that you put in?

A. Yes.

Q. And how many of those have you done?

A. Maybe one.

Q. Would that be within the 12 to 20?

A. Uh-huh.

Q. Okay. That's a "yes"?

A. Yes, yes.

Q. Okay.

A. I'm sorry.

Q. Sometimes you'll say "uh-huh" or --

A. Yeah.

Q. -- "huh-uh" --

A. Right.

Q. -- and she can't get that.

A. I'm sorry.

Q. That's okay.

So you've only operated or had to perform a revision surgery on one transvaginal mesh implant that you put in one of your patients?

A. Yes. Including -- I assume that you're including

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slings -- sling mesh procedures as well as vaginal mesh --
Q. Yes.
A. -- right?
Yes. Okay.
Q. I was speaking more generally.
A. Right, yeah, got it.
Q. And the one product that you had to go perform a revision surgery on, do you know what the product was?
A. It was a sling. It was a -- I can't remember if it was a transobturator or a retropubic, but it was one of my -- it was a -- are you talking about the one that I put in?
Q. Yes.
A. Yeah.
Q. Would it have been a TVT or a TVT-O?
A. Yes. It was probably a TVT. It was early in my career.
Q. What happened on that one -- I guess what went wrong where it required there to be a revision surgery?
MS. DEMING: Objection, form.
A. She began -- she was having some voiding difficulties shortly after the procedure, and I think I removed it within probably two weeks of the implant. She was having difficulty with retention.

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Q. (BY MR. MONSOUR) And does that -- when you have difficulty with retention, does that mean that you as a physician likely put it in too tight?
A. Yes.
MS. BECK: Dr. Shoemaker has to speak up. I really cannot understand what he's saying.
MR. MONSOUR: He's trying. I've got -- we've got the mike in -- we've got the speaker right in front of him. I'm sorry. We're doing all we can.
MS. BECK: Okay.
THE WITNESS: Can you hear -- can you hear Mr. Monsour plainly?
MS. BECK: Yes, I can hear Mr. Monsour pretty clearly, but Dr. Shoemaker evidently speaks very softly --
MS. DEMING: Not really.
MS. BECK: -- and it doesn't carry to the speaker -- or the mike.
THE WITNESS: I'll try to do better.
Q. (BY MR. MONSOUR) So you've done approximately 12 to 20 revision surgeries. You've done one on one that you put on. The remainders that you've done revisions on, were those split amongst both slings and pelvic organ prolapse implants?

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A. Yes.
Q. Okay. More one versus the other?
A. Probably more pelvic organ prolapse materials.
Q. Okay. And do you know -- of the ones that you revised, did you determine what the products were that were originally implanted by the other physicians?
A. Yes.
Q. And how did you do that?
A. Asked -- I reviewed the operative reports from the implanters.
Q. Okay. And do you remember to this day what those were?
A. Almost all of them were the products from AMS, Apogee and Perigee and Monarch slings.
Q. Do you have any opinions as to why the group that ended up with you being the revising doctor mainly tended to be AMS products?
A. First of all, in Corpus, there's no urogynecologists and -- and the -- all of the vaginal floor and pelvic organ prolapse cases are typically done by gynecologists. And the urinary incontinence procedures are typically split between the urologists and the gynecologists.
So the majority of pelvic organ prolapse and

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urinary incontinence cases in our -- in this community are done by gynecologists. And I have -- you know, I know all my colleagues, especially, you know, who have been involved with the pelvic organ prolapse repair. We know each other. And I think some of my colleagues and friends and -- who have been mesh users over the last 15 years or so, I think they for some reason were attracted to the AMS products and that was what they typically used.
And I think -- but why there were more from -- more complications with those cases, I'm not sure.
Q. Okay. When I read your report, there's a section in there where you're kind of talking about -- and most of the products were made by people other than Ethicon that you looked at.
Do you mean to imply -- I just want to clarify this. But do you mean to imply that the products made by AMS are of a lesser quality than the products made by Ethicon?
MS. DEMING: Object to the form.
A. I don't know, quite frankly. I never -- I mean, I saw the Apogee/Perigee products and -- but I never really utilized them. And I was always -- typically if I get involved with a particular product that I like that I'm having good results with, I don't like to switch and

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change back and forth to other things that may -- that I'm told may be better than what I'm currently using, unless I have a particular problem and I'm looking myself to make a change.

Q. (BY MR. MONSOUR) Okay. Of the -- now, you've already told me that you have done a revision surgery on, you believe, a TVT product, correct?

A. Yes.

Q. That was the one that you put in, and that would be manufactured by Ethicon, correct?

A. Yes.

Q. Have you ever done a revision surgery on a Prolift?

MS. DEMING: That he put in?

MR. MONSOUR: (Moving head side to side.)

MS. DEMING: Okay. Thank you.

A. Yes.

Q. (BY MR. MONSOUR) Okay. And when did you -- how many of those have you done?

A. Out of that 12 to 20, maybe 3. These are guesstimates now.

Q. And how were you able to confirm that they were Prolifts that you were operating on?

A. Again, from the operative report --

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Q. Okay.

A. -- of the implanter.

Q. And other than the one TVT that you've mentioned that you put in, have you operated on any other -- performed any revision surgeries of any -- on any other TVT or TVT-O or any other type of TVT product made by Ethicon?

A. Some of the slings that I may have had to revise or remove could have been a TVT or TVT-O sling.

Q. Okay. And one of the things in depositions I -- "could have been" doesn't really help me. I need to know for sure if you know.

MS. DEMING: Object to form.

Q. (BY MR. MONSOUR) Can you say for sure you've operated on a TVT or a TVT-O --

A. I would say, yes, at least one or two.

Q. So if I were to -- if I were to summarize it, you said you've operated on maybe three Prolifts and one or two TVTs and then the other TVT that you mentioned. Is it a fair statement to say that you've probably done revision surgeries on around six Ethicon products?

A. I don't know. I mean, maybe.

Q. Okay.

A. I don't know whether that helps you or not. I --

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I don't really know the answer to that for sure.

Q. I'm just trying to get a ballpark. If I were to tell the jury you've operated on about six, if I'm off, I wouldn't be off by very much, would I?

A. No.

MS. DEMING: Object to the form.

A. No. And -- and remember, since we don't -- I'm -- by default, I get a lot of these pelvic floor problem cases that are in the community. They end up in my office and -- so I get referred a lot of those cases.

Sometimes the problem may not be a complication, but may be a -- or they may be a failure, in other words, a recurrence of their prolapse, so I see those cases as well. But that's not included in the 20 or so mesh revision cases.

Q. (BY MR. MONSOUR) Right, right. With regard to the TVT products, do you still use them today?

A. Yes.

Q. And let's say a patient came to see you today and had stress urinary incontinence. What would you do to treat her?

MS. DEMING: Object to the form.

A. First of all, I would do a complete workup and probably urodynamic studies, determine whether or not --

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and, of course, do an exam to see whether there was any pelvic organ prolapse in addition to her stress incontinence.

Urodynamic studies would help give me an idea of whether her urethral closure pressure or vesicle leak point pressures were -- what they were to try to rule out intrinsic sphincter deficiency, which is something that I need to know because it does make a difference in the way I approach any surgery we might do.

We talk about nonsurgical methods to improve their incontinence, sometimes Kegel exercises, that kind of thing. There's a lot of prolapse associated with it. Then we talk about the use of a pessary, as it may be a first line, depending on the age of the patient and what their sexual activity is.

We try to rule out urgency incontinence as opposed to stress incontinence or whether they have mixed incontinence, which is a combination of both those conditions.

Q. (BY MR. MONSOUR) Okay.

A. And then after all of that, if we decide that surgery is going to be the best approach, then I may make a decision about, as a first line, what kind of sling I'm going to put in. And sometimes it's a TB -- it's a

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retropubic and sometimes it's a transobturator.
Q. But in either case, it will be an Ethicon either TVT or TVT-O, correct?
A. That's correct.
Q. As we -- as we sit here today --
A. Or let me -- let me back up.
Q. Go ahead.
A. As -- in the last couple of years as a transobturator sling, I used -- have been using the TVT Abbrevo product instead of the TVT-O.
Q. Okay. So if a woman came to see you today -- let me clarify this --
A. Okay.
Q. -- and you were going to do -- you were going to surgically manage her stress urinary incontinence, you would either use the TVT retropubic --
A. Correct.
Q. -- or the TVT Abbrevo?
A. Correct.
Q. You would not use today a TVT-O, correct?
A. I had to use one recently because the hospital was out of the Abbrevo and they happened to have a TVT-O available, but my preference would be the Abbrevo.
Q. Okay. Why do you like the Abbrevo over the

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TVT-O?
A. The -- I'm not sure when the Abbrevo product came out, but only because the -- the -- the typical complaint about TVT-O often had to do with transient leg pain after it was applied. And -- and even though I had an occasional patient complain about some groin pain or leg pain, it was always temporary. I never had any with a chronic problem that lasted forever.

The Abbrevo came out to try to eliminate that. I don't know whether you're familiar with that product or not and what it looks like. But the -- it's -- the design of the Abbrevo is that the polypropylene mesh, which I think is identical to the TVT-O mesh, is only 12 millimeter -- 12 centimeters in length. So it actually can penetrate the obturator muscles and obturator membrane on each side.

The way it's designed, you can -- as long as you adjust it so that the midline is right in the midline, then you get an equal amount of mesh on the obturator muscle on each side, and, therefore, there's no mesh that extends into the muscles on the inside of the leg; the idea being that there won't be any -- they use the little polypropylene suture material and then -- so that the patient is left without any kind of -- anything going

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beyond the obturator muscles on each side. So you still get the same support in the mid portion of the urethra, but it doesn't extend beyond the pelvis.
Q. Okay. When did you switch over to preferring the Abbrevo versus the TVT-O?
A. This is 2016. Probably -- I'm -- quite frankly, when -- I'm not sure what year it was introduced. You may have that information. But it may have been -- I want to say two thousand -- maybe '12 or '13, somewhere in that range.
Q. Okay. Now, I was looking on your Web site. Don't you have some other type of procedure you can do for stress urinary incontinence?
A. Well, there may be -- I do -- there is a treatment that I do a lot of for urgency incontinence called sacral nerve stimulation, InterStim.
Q. That's what it was.
A. Yeah, yeah. That's not a procedure for stress incontinence. That's a procedure for urgency.
Q. How many -- give me an idea about how many slings, either TVT or TVT-O, when you have to -- or TVT Abbrevos, about how many of those would you say you're putting in in a given month these days?
A. Maybe eight.

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Q. Is that --
A. Eight to ten, something like that.
Q. Is that pretty consistent?
A. Uh-huh.
Q. Yes?
A. Yes.
Q. Okay.
A. Yes. I'm sorry. Can you hear me?
Q. Now, let's -- let's move from stress urinary incontinence. Let's talk about pelvic organ prolapse. Is it -- is it a fair statement to say that you have stopped using pelvic organ prolapse kits to treat pelvic organ prolapse?
A. Synthetic kit, yes.
Q. And when did you stop using the pelvic organ prolapse kits to treat pelvic organ prolapse?
A. Probably 2012 when Ethicon quit manufacturing the Prolift products.
Q. And why did you decide to quit using those kits?
A. Well, there's -- the main reason was because the -- as I tell people, sometimes there's not enough trees in South Texas to get the -- to get -- to put the informed consent in front of a patient to use polypropylene mesh anymore since all this litigation

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began.
Q. Okay.
A. And I didn't have enough paper that I could find to -- so, you know, we were sit -- and the hospital quit buying them. When the litigation began, the hospital wouldn't allow the kits to be even brought into the -- into central supply.
So, anyway, that affected everybody that was using any kind of synthetic meshes, so that's when we quit.
Q. Okay. So if I was going to boil it down to the reason you quit using pelvic organ prolapse kits to treat pelvic organ prolapse, it would be, No. 1, the informed consent process got to be too, too much and, No. 2, the hospitals weren't allowing them anymore?
A. Correct.
MS. DEMING: Object to the form.
Q. (BY MR. MONSOUR) Any other reasons?
A. Not really.
Q. Okay. Did you ever use any other pelvic organ prolapse kits other than Prolift?
A. Yes.
Q. And which did you use?
A. I used a Prosima.

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Q. And who made Prosima?
A. That's an Ethicon product.
Q. Okay. And why did you use Prosima?
A. Prosima was a new generation that did not have the little straps on the polypropylene -- the body of the mesh, and it was -- had a totally different design so that the -- you wouldn't use any trocars to implant the mesh. So it was a totally different design.
Are you familiar with it? I don't -- what we do is we do a dissection and then the way the material was placed was with a special instrument that came in the kits. So you could actually put the wings out toward the ischial spines on each side, whether it was an anterior or posterior kit, and that would allow the mesh to lay perfectly nice and flat under the bladder or over the rectum that -- and so -- without any straps and without any necessity to put any -- to suture it in place, which was an attractive mechanism for -- for implanting it and made it simpler and easier.
And then on top of that, then you -- what kept the device in place was a -- called a vaginal support device, a VSD, which is a little device you put into the vagina and sutured it in temporarily for about three weeks and then you took it out in the office.

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Q. What year did you start using pelvic organ prolapse kits to treat pelvic organ prolapse?
A. Probably two thousand -- I want to say maybe late 2006, maybe early 2007 was the Prolift.
Q. And then you stopped in 2012?
A. And then -- yes.
And then I was using some +M kits, which were identical in terms of the way they were applied and implanted, and I think that was base -- maybe 2009.
And then the Prosima kits were designed for patients with minimal prolapse. They weren't really designed for patients with severe prolapse. And so that was another tool that we had available. And I think that -- that must have been 2010 when -- I'm going to guess, two thousand -- late 2009, 2010 when Prosima became available. And so I only used it for a short -- relatively short period of time.
Q. Can you give me an idea of how many of these kits you implanted between 2006 to 2012 when you were using them?
A. I'm going to probably -- probably well over 100.
Q. Can you narrow it down any more than that?
A. Well, let me think. 2006 to 2012, over a six-year period, that's actually about 200. I'm going to

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say -- because I was thinking about 40 a year, so that's about right. I would say 200, in that -- between 200 -- a little over 200, 200 to 240. That's about 40 a year for six years.
Q. Okay. As far as slings, polypropylene slings that you've implanted, whether it's the TVT, the TVT-O, or the Abbrevo, how many of those have you implanted over the years, would you say?
A. I would say probably 100, at least 100 a year, 100 to 150 a year, so that's a lot, maybe -- and I think we started using slings maybe 2002, 2003, something like that.
Q. It's good you anticipated my next question.
MS. DEMING: Don't do that. Let him ask the question.
THE WITNESS: I knew it was coming.
MS. DEMING: No, you don't.
(Phone ringing.)
MS. DEMING: Sorry.
A. And I think that's it's been a while since I've thought about these numbers.
Q. (BY MR. MONSOUR) So -- and just -- just so I can get an idea, if I do those numbers in my head, you've probably safely put in well over a thousand polypropylene

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slings in your career?
MS. DEMING: Object to the form.
A. Yes.
Q. (BY MR. MONSOUR) Okay. And it might be as high as 1,500 or more?
A. Yes.
Q. Have you ever heard from any other doctors that, hey, just wanted you to know one of your clients or one of your patients has come in and I'm having to operate on her sling or her mesh implant that was placed by you in her?
A. No.
Q. As far as -- as far as your patients that you've implanted transvaginal mesh devices in, whether it be a pelvic organ prolapse kit or a sling, a polypropylene sling, how many are you aware are having problems with those products?
A. I have one patient that -- no, that was a different -- that was different. That was since 2012.
I don't know of any. I don't know of any -- I do not have an awareness of any patient who is having a product -- who is having a problem with any implanted sling or mesh that I'm aware of.
Q. Does that help shape some of the opinions that you might have about using these products?

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A. I'm sorry. I don't understand.
Q. I believe -- you use TVT and TVT Abbrevo and occasionally TVT-O because you think those are good products, I'm assuming?
A. Yes.
Q. If you found out that more of your patients were having problems with them, could that alter your opinion of that?
A. If I had -- yes, if I had patients who were having big problems with any type of surgery that I was doing, then that would -- it would make my opinion about the type of surgery I'm doing somewhat different, yes.
Q. Okay. As far as the surgeries that you've done -- and you explained to me about 12 to 20 revision surgeries that you've done -- can you walk me through some of the complaints that the women were having with their implants that required you to go in and surgically operate on them?
A. Probably the most common complaint was erosion or discharge or they'd already been diagnosed with erosion by another physician and was being referred to me for management and -- and then a lot of -- and then probably another more common reason would be the patients' husbands or their sexual partner complaining that they could feel

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it.
Q. When someone comes to see you and they're saying, hey, my husband says he feels something when we have sex, what type of surgery do you do to fix that problem?
A. Well, it depends on what the problem is. If I do a very thorough exam and I feel like -- you're talking about a patient that has mesh or --
Q. Yes, sir.
A. Obviously if there's a mesh erosion and he's feeling it, then there's not really -- let me back up.
If it's a recent procedure and there is a small erosion, oftentimes, I will attempt to manage that with estrogen therapy.
Q. Okay.
A. And -- and then if it doesn't improve, then we go to the operating room and remove that section or segment of the mesh.
Q. Now, when you remove a portion of the mesh to treat a condition like that, that is obviously removing a portion of the mesh that was providing support in the patient's vaginal area, correct?
A. Correct.
Q. How does that allow the product to still serve its initial purpose if you're having to cut part of it

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out?
A. That's a good question. The -- you would think that prolapse would be imminent if you remove a portion of the mesh that was designed to support the pelvic floor. Sometimes that happens. And I warn patients that that may happen and then sometimes it doesn't. You remove a piece of it, you correct the vaginal tissue over the defect that you've created from the removal of the mesh, and sometimes they don't lose support.
I think it depends on where the -- where it's located and the volume of mesh that you have to remove.
Q. Okay. Now, let's go back to kind of the same line of questioning I asked you about stress urinary incontinence. A woman walks into your office today and has pelvic organ prolapse. You're not going to use, as we sit here today, a pelvic organ prolapse transvaginal mesh polypropylene kit today, correct?
A. Correct.
Q. What are you going to offer her if she needs a surgical option?
A. Since 2012, I've been doing basically native tissue repair and -- and have been -- as an adjunct to the native tissue repair, I've been using a biologic material

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called MatriStem, which is a noncross-linked extra cellular matrix product to help improve the efficacy and the efficiency of the repair.

And then it depends on what the defects are in terms of how I manage. If they have an apical defect, they need to have that supported in some way, so it may be a sacrospinous fixation or it may be -- or if it's a pretty significant prolapse, I may resort to a sacrocolpopexy, which, by the way, is -- does involve a polypropylene mesh product put in robotically with the -- but abdominally.

Q. You actually have one of those on your Web site.

A. (Moving head up and down.)

Q. Correct?

A. What -- which --

Q. A sacrocolpopexy surgery.

A. Yes.

Q. I watched it.

A. Oh, you did? That's right. I do have that on the video.

MS. DEMING: Did you like it?

MR. MONSOUR: Did I like it?

MS. DEMING: Did you enjoy it?

MR. MONSOUR: That's not one of those things

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you like or dislike. I watched it. But -- okay. So I would -- yeah, I'll just --

MS. DEMING: I didn't mean that quite the way it sounded, but it's a very good -- I've seen it, too, and he does a very nice job.

Q. (BY MR. MONSOUR) But if we can go through it, you've got -- on your Web site, you've got a sacrocolpopexy procedure --

A. Correct.

Q. -- where you are doing the surgery robotically, correct?

A. Correct, that is right.

Q. And if we watch the procedure, we can see you, like, tying knots using the robotic hands, correctly?

A. Correct.

Q. And how do you do that with the robotic hands? Do you have something that hooks onto your hands and allows them to mimic your fingers or how does that work?

A. The -- that's a whole different technology. But you -- it's a laparoscopic procedure. So the patient has ports that are placed through which these instruments that will do the -- that do the dissection and instruments that do the knot tying, et cetera, and then that's attached to a robotic machine that actually controls the instruments.

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Then I control the machine sitting at a totally different location through a -- it's kind of a station where it's kind of like playing a video game and you have little finger devices that -- that you use to manipulate the arms of the robot.

Q. Okay. How far away are you from the patient physically?

A. Probably 10 to 15 feet.

Q. Okay.

A. It's in the same -- but the operating room is set up so you could actually do it in another room, I mean, if you had to. So it's --

Q. You could do it from India if you had to, I guess, if they had the technology, right?

A. Yes.

Q. Are there nurses that are next to the patient as you're doing the procedure to do what nurses do in surgery?

A. Yes.

Q. Okay.

A. There's an assistant. I usually have two assistants. And then usually -- and, of course, anesthesia's there.

Q. And why are you doing these robotic surgeries

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instead of doing it the old-fashioned way?

A. Well, robotically, the patients have a much faster, shorter recovery. Instead of having a large incision, they only have five small 1-centimeter incisions. So they're often -- we can actually discharge them within 24 hours of their hospitalization.

Q. Now, in watching your sacrocolpopexy surgery on your Web site, you do use a polypropylene mesh?

A. Yes.

Q. And what type of polypropylene mesh do you use?

A. It also is an Ethicon product called ARTISYN.

Q. A-r-t-i-s-a-n?

A. I think it's A-R-T-I-S-Y-N, ARTISYN.

Q. And why do you use that product in your sacrocolpopexy surgeries?

A. Well --

MS. DEMING: Object to the form.

A. The -- it's a Y mesh that's already been designed so you don't have to craft it. And there are some features about that mesh, one of which it's a +M. It's a +M or ULTRAPRO mesh so that the -- so that it does have a Monocryl component that does dissolve.

So the mesh ultimately is very -- after about 90 days is very lightweight and has a big pore size.

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It's a good -- it's identical to the +M product that we were using vaginally. And as a result, it also has -- the way it's designed, it has little measurement lines on it that are centimeters -- that it's a centimeter apart so you know exactly what the length of the mesh is that you're applying at the time you put it in.

So when you craft it or have to shorten it or leave length to it, it's easy to manage, and when you do it -- when it's in the pelvis and you're looking at it robotically from the console that you're sitting in, it's real easy to see where you are --

Q. Okay.

A. -- keep yourself oriented.

Q. Okay. And you use a Gore-Tex stitch, correct?

A. Yes.

Q. Why do you use Gore-Tex instead of polypropylene?

A. Well, Gore-Tex is a permanent -- that's what -- the reason I use Gore-Tex is because in the conventional sacrocolpopexy procedures that were done prior to a robotic surgery being available, that was the technique and the design that they -- that was utilized.

Q. A Gore-Tex stitch?

A. A Gore-Tex stitch.

So I wanted to try to keep it as close to

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the identical procedure that was originally described in terms of the manner in which the product -- the polypropylene was put in. But I've also done them -- I've also done them with some -- some absorbable sutures, too.

It -- it varies depending on where I am, whether the patient has had previous surgeries before, whether they've still got a cervix or not, whether they've -- whether there's a -- a lot of different things that make the decision about what type of suture material is used.

Q. Now, you had mentioned earlier that one of the treatments that you offer some of your patients for pelvic organ prolapse is -- is a -- is a biologic?

A. Yes.

Q. And what's it called, again?

A. It's -- the company that makes it is called ACell, A-C-e-l-l. And the product is called MatriStem. It's a -- it's a xenograft that's -- that's designed from urinary bladder matrix. It's an extracellular matrix product.

Q. And how do you implant that?

A. It's implanted vaginally as well. And I do craft -- it comes in sheets and it does -- what it does that's different as a typical biologic, it is not the

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product that's designed to be the support in the pelvic organ prolapse. It actually -- it's a graft and it actually disappears in about 90 days itself.

But in the process, it -- and it's decellularized so that the collagen matrix that makes up this graft actually directs the immune cells that come to the healing process to remodel into the identical tissue it happens to be sitting on.

Q. Okay. Now, the mesh that is being used for pelvic organ prolapse by you, the two implants that you use, one is the MatriStem, the other one would be the ARTISYN, correct?

MS. DEMING: Object to the form.

A. Well, yes. One is designed for sacrocolpopexy and one is designed to put in vaginally.

Q. (BY MR. MONSOUR) How do you put in the one -- the MatriStem which is designed to be put in vaginally?

A. I put it in very similar to the way I put in I want to say Prolift except it doesn't have any arms or trocars or anything, but you make the same type of incision and dissect between the bladder and the vagina and -- or if you're doing it posteriorly, between the rectum and the vagina, and you create a space all the way out to the -- it's a full thickness dissection.

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And then I do a native tissue repair just like you ordinarily would with -- like an anterior or posterior colporrhaphy, and then I lay -- so that I create as much connective tissue in that space as I can lay in that space, and then this graft is then placed over that and then the vagina is closed over the graft.

So the graft is laying up against the bladder wall or have this connective visceral -- we call it visceral connective tissue that's in that space, or over the rectal wall and that connective tissue, and then that's -- that's what directs -- the graft then directs the remodeling of the tissue to simulate that connective tissue that's in that space.

Q. And for that procedure, why --

MS. DEMING: Speak up, please.

Q. (BY MR. MONSOUR) Why do you elect to use the MatriStem instead of a polypropylene mesh?

A. The -- first of all, the hospital has no polypropylene mesh to be applied vaginally. And when I was -- when I was still using Prolift or Prosima before they were removed from the market, I would use this MatriStem to lay over the polypropylene graft in a small -- not in a big -- in a -- in a small dimension area to try to improve the thickness of the vaginal wall over

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the -- right at the suture line. That would help -- the whole idea was to try to improve erosion risk -- or I'm sorry, exposure risk.

Q. (BY MR. MONSOUR) Okay.

A. So I already had some experience with that material from that standpoint. But I only had been using it for about a year during 2011. So I had that experience with that particular material, and then I was very -- knowing that -- going back to native tissue repair, we already had some data that showed up to 30 to 40 percent failure in a lot of these anterior and posterior colporrhaphies.

So the notion was, in my opinion, to do a native tissue, and then if we could improve that by adding the -- this MatriStem graft to help improve the connective tissue that was in the support, that it might improve the -- that outcome so that instead of a 30 to 40 percent failure rate, it would be reduced to some degree.

Q. Has it worked?

A. So far. It seems to be -- it seems to be working fairly well. I've been using it since 2012, so it's about three years now, a little over three years. And I've had, you know, a couple of failures, but not anywhere close to the 30 or 40 percent failure rate.

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Q. Okay. So you had mentioned before, the hospital that you practice at does not allow polypropylene mesh to be implanted transvaginally anymore, correct?

A. Well, they don't purchase it, so it's not available.

Q. Okay. But there are abdominal polypropylene meshes at the hospital, correct?

MS. DEMING: Object to the form.

A. I think there -- I don't -- quite frankly, I'm not sure. I would -- I think they are. I'm not sure what -- since I really don't do abdominal hernia surgery, I don't know what my surgery -- surgeon colleagues are utilizing, so . . .

Q. (BY MR. MONSOUR) Is -- are you familiar with how -- how Ethicon's transvaginal polypropylene meshes compare to their abdominal polypropylene meshes?

A. Do I know how they compare?

Q. Yes.

MS. DEMING: Object to form.

A. No, I do not.

Q. (BY MR. MONSOUR) Do you know what the differences are between the vaginal and the abdominal meshes that they make?

A. No, I do not.

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Q. If the meshes were identical, would -- would you utilize information about the abdominal meshes in determining whether or not -- well, let me ask -- that's a crummy question. Let me -- let me start again.

MS. DEMING: He knew I was going to object.

Q. (BY MR. MONSOUR) Do you think -- if the abdominal -- if the abdominal and transvaginal meshes, polypropylene meshes by Ethicon, were identical, would you or could you use information about the physical characteristics of the abdominal placement to give you an idea of how the product might work vaginally?

MS. DEMING: Object to the form.

A. There's two different locations, and there are different -- there are different mechanisms in which you're trying -- you know, a hernia repair in the abdomen is a lot different than the hernia in the pelvic floor that's allowed a prolapse of the bladder and rectum, et cetera. So -- and the vagina is a different arena, you know, in any kind of surgery.

So I don't -- I don't think that because there were certain characteristics about anything that's used in the abdominal hernia arena necessarily would automatically apply positively to repairs in the vagina.

Q. (BY MR. MONSOUR) You mentioned they're very

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different, the abdomen -- the surgery in the abdomen versus surgery in the vagina, correct?

MS. DEMING: Object to the form.

A. Yes.

Q. (BY MR. MONSOUR) Could you tell me why they're so different?

A. Well, the vagina is a different organ. You know, it's a different organ and it functions differently. And so it's -- it's like, you know, what might be an appropriate application in operating on the stomach, you're trying to -- to see if that would apply to open-heart surgery. It's -- it's not the same and it functions differently.

The vagina functions different -- it's not just -- the abdominal wall just is designed to hold the abdominal contents in the right location, and the vagina does a lot more things than just hold up the pelvic floor organs.

Q. Right. Okay. We've been going for about an hour. Why don't we take a break.

(Short recess.)

Q. (BY MR. MONSOUR) Dr. Shoemaker, we've had a short break. Are you ready to proceed?

A. Yes.

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Q. Okay. We were talking about different types of meshes at the end, abdominal versus transvaginal. Do you remember that?
A. Yes.
Q. One of the questions I'd like to ask you is your knowledge -- some of the things that you talk about in your expert report reference basically your experience implanting and explanting or implanting and revising transvaginal mesh products, correct?
A. Yes.
Q. Now, when you were performing the revisions that we've already talked about, the 12 to 20 revision surgeries that you've done, did you look at the mesh that you were revising?
MS. DEMING: Object to form.
A. You mean after it was removed?
Q. (BY MR. MONSOUR) Yes, sir.
A. Yeah.
Q. And did you perform any testing of it?
A. No.
Q. Did you just look at it visually?
A. Yes.
Q. And can you tell us what you would see when you looked at it?

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MS. DEMING: Object to the form.
A. Well, you would -- you would see -- you could identify the mesh, you could see that it was -- you know, it was a mesh like a -- like a matrix, in other words, it was -- you could see the fibers, and then you could see -- you know, you never could -- typically, it was several months to a year -- years after the implantations. And so there would be a lot of scar tissue around -- around it that we were having to dissect through in order to get the products out, uh-huh. And it would be various lengths.
Q. (BY MR. MONSOUR) The -- some of the things that you talk about in your expert report are pore size, correct?
A. Yes.
Q. Before this -- before you were retained as an expert by Ethicon, did you ever talk about pore size?
MS. DEMING: Object to the form.
A. You mean -- I'm not sure I understand what -- talk to who about pore size?
Q. (BY MR. MONSOUR) Did you ever -- did you ever -- did you ever talk with any other doctors about pore size or anything like that? Is that a topic that would come up?
A. If we were in meetings and things and we were

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talking about different types of products and you were listening to lectures about pelvic floor reconstruction and pelvic floor meshes, we would absolutely talk about pore size.
Q. Why is that important?
A. Well, the whole concept of using a synthetic mesh in order to improve pelvic organ prolapse repair is that you want to have the mesh integrated into the patient's body and not allow -- and not -- you don't -- what you don't want is to have a product that gets encapsulated and scarred. But you'd prefer to have a product that -- and so pore size was important.
The -- in order for the body to put in the vasculature and the collagen to integrate that product or that particular scaffold to help in the support, you wanted to make sure that the pore size -- if it was too big, there is such a -- if the pore size was too big, then you didn't have any support, and if it was too small, then it typically would not integrate.
Q. Are you going to be an expert and try and give opinions about pore sizes?
A. If I'm asked what I know about pore sizes and why I think that's important, yes.
Q. Do you think you're an expert in pore sizes?

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A. An -- what do you mean by that?
Q. I mean, do you think you're qualified to give opinions about pore sizes and how tissues integrate into those pores?
A. In terms of the --
MS. DEMING: Object to the form.
A. In terms of the -- the pore size related to pelvic mesh and its integration into the type of surgery that I do in terms of pelvic organ prolapse, absolutely, I feel very good about that, being able to talk about that.
Q. (BY MR. MONSOUR) How -- how big are the pores on -- in TVT mesh?
A. I think in terms of microns, it's probably in the -- I want to say 1,300. I can't -- we had that the other day, 1,300 microns, something like that. It's -- it's almost -- it's 2 millimeters.
Q. What -- for -- for integration within the pelvic floor, what size of pore is too small and what size is too big?
A. I think that's been defined -- I think the definition is 75 is the -- sort of the magic number. If it was less than 75 microns, it was considered smaller pores or microporous, and if it's larger than 75 microns, it's considered macroporous.

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Q. I guess my definition -- I mean, my question is a little simpler than that. You're talking about the Amid article, correct?
A. Correct.
Q. A-m-i-d, I think?
MS. DEMING: You have to answer verbally. Was that a "yes"?
A. Yes.
MS. DEMING: Okay.
Q. (BY MR. MONSOUR) But I guess -- are -- are you saying -- is it your opinion that a pore -- I think the Amid article says 75 microns is -- bigger than that is macroporous, correct?
A. Yes.
Q. So would it be your opinion that if something was, like, 79 microns, that would be an adequate pore size for a mesh?
A. I'm not sure what "adequate" means.
Q. To allow for tissue end growth to get good response.
A. I don't have any experience with -- really with any mesh that is smaller than what the Ethicon mesh is. So --
Q. So --

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A. -- I would -- without that -- so I don't know. I know that when pore size is discussed and we know what the -- what we would like to see happen with integration, the bigger the better to a certain degree, and then obviously it's sort of just common knowledge if you get too big, then you don't -- then you don't have any support.
Q. But here's -- here's -- this is the basis of my question. This is why I'm asking you, because I don't know exactly what Ms. Deming will ask you on the stand. I have an idea, but I don't know everything and I don't know what answer you're going to give. And so some of the questions I have to ask you are what are you going to talk about.
And one of the things that I need to find out is, you know, how much do you really know about pore size and its role in integration with tissue?
MS. DEMING: Object to the form, asked and answered.
Q. (BY MR. MONSOUR) And is it -- you know, what size of pore is too small and what size of pore is too big to effectively work in the pelvic floor? I guess that's what I'm getting at.
A. Prior to using some of the Prolift products, I

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did have some experience with a -- some biologics that were cross-linked biologics that really had small pore sizes, and I abandoned their use because they oftentimes would encapsulate -- they never would get integrated in the tissue and then they would ultimately fail.
So I do have some personal experience with products that are tiny in terms of pore size. I have no idea whether they were 75 microns or whether they were 74 microns. My -- I can tell you from my discussion with my peers at meetings and things that the Amid article at 75 seemed to be the goal -- the standard by which these pore sizes were measured.
And I know that the Prolift products and the TVT-O products were exceed -- certainly would be classified as macroporous and that they seemed to work extremely well in terms of being able to integrate into the tissue when placed properly.
Q. So the -- the smaller pore products that you worked with were not polypropylene products, they were biologics?
A. That's right.
Q. One of the things we have to do is we have to figure the basis for your knowledge. Is the basis for your knowledge on pore size pretty much the Amid article?

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A. And my experience --
Q. Okay.
A. -- and what the -- and the -- you know, the studies and things that I've reviewed in my, you know, participation in some of these conferences, et cetera.
Q. Okay. So the Amid article I can pull up and I can look at. I can't really pull up your experience and look at it, but I can -- I can ask you about it.
As far as your experience, what is it about your experience that you believe would allow you to be an expert on pore size? And -- and here's -- and I'll be a little more specific.
Is your experience, Hey, I've worked with some of these Ethicon products, I put them in, the pore seems to be good, so, therefore, I know about pores, or do you actually really know something about differences in pore size and those types of things?
MS. DEMING: Object to the form.
A. Well, you can certainly look at it and see, you know -- I can certainly look at the mesh every time I utilize it. And -- and, you know, none of the -- none of the -- any study that you read about certain types of meshes that were being introduced back at the early 2000s, sometimes there would be conferences that we would --

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there would be discussions about why certain meshes work better than others and a lot of times the concept of pore size would come up.

So the fact that the pore size and the Amid article indicates that the 75 micrograms was picked, that anything over than was macroporous, most people have had in their experience and what they wrote about in terms of their -- what they would utilize in some of these clinical trials, they would typically want to use a macroporous product. And the clinical trials that we saw, the results seemed to be good and it was consistent with what I was seeing in my patients. I wasn't seeing patients come back with big-time failures.

And, like I said, the time -- the couple of times that I used products that were really tiny porous materials, I quit using them quite early on.

Q. (BY MR. MONSOUR) But back -- that's kind of where I'm getting at. The -- if the Amid article talks about 75 microns and you had said before you think the pores in TVT are about 1,300 microns --

A. I think that's right.

Q. The number that's sticking in my head is, like, 1,379 or something like that.

A. Okay.

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MR. MONSOUR: Do you know off the top of your head?

MS. DEMING: (Moving head side to side.)

MR. MONSOUR: Okay.

Q. (BY MR. MONSOUR) I think you're right. I think it's in the 1,300s, but if it's in the 1,300s, that's roughly 14 times the size of 75 microns, correct?

MS. DEMING: Object to form.

Q. (BY MR. MONSOUR) Right?

A. Yes.

Q. And I guess that's what I'm getting at. That's not slightly bigger than 75 microns, that's roughly 14 times bigger, if my math is correct, right?

A. Yes.

Q. And so I guess that's where we -- that's what I'm trying to figure out is obviously Ethicon didn't say, okay, bigger than 75 works, so we're going to make it 78. For some reason, they have picked the size that they picked, which is -- we'll say is ballpark of 1,300 microns.

My question to you is: Why is 1,300 -- why is that a good number or size for a pore? That's kind of what I'm getting at.

A. I'm not -- I'm not sure. It just simply means

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that it's -- it's -- it falls into the category of being macroporous, and when investigators sit around and talk about various products and which ones work, seem to be the best, then they -- they use the words "macroporous" versus "microporous," and that's been set up as the criteria of what's macroporous and what's not.

Q. The meshes -- the mesh that you use now for sacrocolpopexy, the ARTISYN, how -- what are the size of the pores in that?

A. It's about -- it's -- it's a plus -- it's the Prolift +M mesh, so whatever that pore size is. I think it may be -- it starts out at 1,300, but it increase -- or, yeah, in that -- but the -- since the big part of the fibers are absorbable Monocryl fibers at the pore size, once in 90 days is even larger.

Q. Do you know after 90 days how large the pores get?

A. I want to say 2,400, 2,500, something like that.

Q. So when it goes in, it has about the same pore size when you factor in the Monocryl as the TVT, and then once the Monocryl dissolves or absorbs, it has a much larger pore?

MS. DEMING: Object to the form.

A. Yes.

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Q. (BY MR. MONSOUR) If I look in your reports, it appears that one of the things you're talking about is the physician that implants the product can have a significant role as to whether or not the product -- the transvaginal mesh product functions well inside the woman; is that true?

A. Yes.

Q. Do you believe that in most cases where a woman is having problems with her transvaginal mesh implant, that in most cases it's more of an issue of physician problems versus product problems?

MS. DEMING: Object to the form.

A. It may not -- it's a little more complex than that. The physician does play a big role, but there can be other complications that can occur in the surgery that's just part of surgery that can influence whether or not the product is adequate or has complication with it as well.

Q. (BY MR. MONSOUR) Give me -- give me an example of some of the things that can take place in surgery that can affect how -- what the outcome is.

A. You can have hematomas form. It breaks down the wound. Anything that has to do with the -- with -- that can influence the way the vagina heals can influence some

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of the complications with the mesh. Some of that has to do with the vascularity to the tissue that you're trying to repair over the mesh when you're pulling, the position of the mesh in the tissue, whether or not a hematoma develops as a result that doesn't even -- you may not even see it until after the patient has gone to recovery or may not even see it for several days after she's home that can break down the wound, the vaginal wound that's been repaired.

Q. What's a hematoma?

A. That's a -- that is a mass -- a mass of a blood clot that occurs at the operative site where blood vessels have been disrupted and the blood collects there and it forms almost a mass like a tumor. That's why the -- the suffix "oma" is applied. So it's a -- it's a hemorrhage that occurs at the operative site.

Q. Okay. How -- how often do patients suffer from hematomas when they're having transvaginal mesh products implanted in them?

A. A lot of the study -- you know, if you read some of the studies, they'll often talk about blood loss, but you don't necessarily see them defined as hematomas. But I think they -- I don't know what the number is, but I can tell you that I've had maybe two hematomas occur in

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vaginal mesh surgery that ended up disrupting the suture line where the vagina comes together.

Q. Okay. And to put that in context, if we add up the number of slings that you've implanted and the number of pelvic organ prolapse kits you've implanted, the number's well over a thousand, correct?

MS. DEMING: Object to the form.

A. Yes.

Q. (BY MR. MONSOUR) So if you've only had two out of well over a thousand, it's a fraction of a percent where we see issues of hematomas affecting the -- the -- how well the implant performs?

MS. DEMING: Objection, form.

A. Well, the hematoma is a -- influences the healing process of the vagina that's been overlaying the implant, and that can make a difference in some complication with the implant.

Q. (BY MR. MONSOUR) Right.

A. But -- but just because I've only had two doesn't mean that that -- the rest of the world -- there may be more than that.

Q. Okay.

A. That's a pretty low number.

Q. So -- but I guess what I'm getting at is, you

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know, I'm trying to figure out, you know, if -- what I'm trying to figure out is there's a lot of women who have lawsuits involving transvaginal mesh products. You're aware of that, correct?

MS. DEMING: Object to the form.

A. Yes.

Q. (BY MR. MONSOUR) Several thousand -- tens of thousands, correct?

MS. DEMING: Object to the form.

A. I don't know the number.

Q. (BY MR. MONSOUR) Okay. I'll represent to you -- and I'm not lying -- it's tens of thousands of women, okay?

MS. DEMING: Object to the form.

Q. (BY MR. MONSOUR) If that's the case, and there's all these complaints out there, what I'm trying to figure out is, is what's causing the problem in your opinion. Why are so many women having problems? That's literally all I'm trying to figure out. And what I'm trying to figure out is, is it the product, is it the doctor, is it something else?

MS. DEMING: Object to the form.

Q. (BY MR. MONSOUR) And so what I want to do is I just want to kind of walk through those. Do you think --

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do you think the products themselves, the transvaginal mesh products, are the reason that so many women are having issues with transvaginal mesh implants?

MS. DEMING: Object to the form.

A. Well, it depends on what their particular complaint is. I think that if -- I don't think you can just say automatically that it's -- it's related to something about the mesh. I think there is a much, much bigger influence in terms of the way the mesh was applied, the way the mesh was inserted, certain things that happen to the mesh when it's inserted improperly, and then there's a -- several -- several other problems that can occur in the healing process.

Anything that happens that doesn't allow the mesh to be integrated into the tissue in which it's implanted can influence a complication with the mesh or a failure of the mesh.

Q. (BY MR. MONSOUR) Okay. All right. So this is why I'm asking you the question, because you -- when you say, well, one of the things that can -- one of the things that can contribute to these women's complaints is you said the way it is applied or inserted, those are your words, correct?

MS. DEMING: Object to the form.

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A. Yes.
Q. (BY MR. MONSOUR) To me, that implies potentially operator error, in other words, the doctor might not have done a great job putting it in. That's what I hear when you tell me that.
A. (Moving head up and down.)
Q. Am I close?
A. Yeah, I think that plays a big role.
Q. Okay. So the doctors can play a big role in the women having poor outcomes. You agree with that?
A. Yes.
Q. You've also mentioned the healing process can play a big role in how the women respond to the implants, correct?
A. Yes.
Q. What about the healing process other than hematomas, which you've already explained, can cause the women to have problems?
A. Anything that disturbs the vascularity of the area and the site in which the surgery's done and the implant is placed, anything -- vascularity of that area is really very, very important. So hematoma's disrupted. Infection, if they get an infection in that area where the -- and I'm talking about the incision line in the

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vagina which has been opened up into the -- into the -- to create the space in which the implant is placed.
So anything that disrupts the blood supply to that area. Could be the vaginal tissue is already anemic, in other words, it's very atrophic or it's very thin, and there's not much blood supply that can increase the risk of the -- of the incision line breaking down.
A infection that occurs at the time of the -- acute infection that occurs at the time of surgery can influence the breakdown of the tissue. If the implant is placed too superficial and it's not really in the correct location, between the organ, the bladder, and the vagina, can make a huge difference in terms of whether there's a good vascularity into the vaginal healing process.
The suture material used to close the vagina can make a difference in whether there's a -- and how -- and how tight the -- and the way the suture material is placed can influence the vascularity of that area.
If the mesh is inadvertently manipulated by the surgeon in a way to shrink or to reduce the pore size can make an influence -- can influence the way the graft itself is placed and can influence the way it's integrated, so there's a lot of factors. If the graft is

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placed correctly and it's in the right place and there's good vascularity and there's not a hematoma, those patients typically do great.
Q. So let's -- let's take a -- let's take a situation where -- I'm going to go out on a limb and I'm going to say that you think you're a pretty good doctor. Is that a fair statement?
MS. DEMING: Object to the form.
A. Okay. I don't have any idea what all this means. But, yes, I do.
Q. (BY MR. MONSOUR) Okay.
MS. DEMING: I just have to make objections for the record, Doctor.
THE WITNESS: That's fine.
Q. (BY MR. MONSOUR) And I just want it to be noted that your own lawyer objected to that.
MS. DEMING: The objection was based on his telling you what he feels about things. That doesn't have anything to -- you don't know that, so that's where the objection -- he is a fine doctor, let me state on the record.
Q. (BY MR. MONSOUR) So we're going to go with that. Your lawyer says you're a fine doctor. And we'll -- we'll say -- let's assume that that's correct.

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Let's say you've got a surgery -- you're a fine doctor. You've been doing this for decades. And you put in one of these mesh implants. You don't have any issues with infection, atrophic tissue, there's no infections that take place during the surgery, there's no superficial placement, you've put it in right, the suture material, the suturing is all done right, you don't inadvertently manipulate the implant in a way that affects the pore size.
If you as a good surgeon put it in and you don't have any of those factors, yet the client -- the patient still has problems down the road from the implant, would that indicate to you that the problem's probably more to do with the implant?
MS. DEMING: Object to the form.
A. It would depend completely on what the problem is.
Q. (BY MR. MONSOUR) But I guess --
A. I mean -- I mean -- I mean, I don't -- I don't understand what the -- I mean, before I could answer that, I'd have to know what the particular problem is.
Q. Let's assume that the woman down the road is suffering from pain, pain in the area of the implant. Would you assume that that problem would be more related

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to the implant than to the doctor that put it in?
MS. DEMING: Object to the form.
A. There are tons of reasons why women may have chronic pain or pain, and I would not just assume that it's related to the implant.
Q. (BY MR. MONSOUR) Okay. Have you seen circumstances where women have had chronic pain that you have associated with their implant?
MS. DEMING: Object to the form.
A. Are you talking about -- just pain in general and not necessarily with intercourse, they're just standing around and they're hurting all the time?
Q. (BY MR. MONSOUR) Let's start with pain in general first.
A. Okay.
Q. Have you seen that situation?
A. I have not.
Q. Okay. Have you seen a situation where a woman has pain with intercourse that is long-term, chronic, associated with her transvaginal mesh implant?
A. I have heard of that -- of patients complaining of that, and I have examined patients complaining of that, and most -- I would say almost all of the time I can feel something that doesn't -- about the way the implant was

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placed. So I can't tell you that I've got -- automatically that if she's complaining of painful intercourse, that it automatically is related to the mesh when all of those other criteria have been met.
Q. Okay. So in situations where you've examined women that have chronic complaints of dyspareunia associated with their implant, you've been able to feel something about the implant that leads you to believe it was placed improperly?
MS. DEMING: Object to the form.
Q. (BY MR. MONSOUR) Is that accurate?
A. Well, if they -- if the patient comes in and that's their main complaint and then -- and I do an examination, you sort of have to rule out all the other reasons that they may have pain with intercourse and how many other surgery -- there can be lots and lots and lots of different things that influence that.
If -- if they -- if I see -- on the examination, I can see an addition to their pain complaint, they have an erosion or they can palpate the mesh underneath the vaginal wall or it's -- and it's -- and they have point tenderness right over that spot, then -- then I can make the assumption that it may be mesh related, and it most like -- it is most invariably the way

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it was -- the way it was implanted.
Q. Okay. You probably will anticipate this question, so I'm going to ask it. How can you tell simply by touching it?
MS. DEMING: In the instance he's describing?
MR. MONSOUR: Yes.
A. Well, you can -- when you do the exam and you feel that everything in the vagina's soft and pliable and mobile and not tender and then you reach a spot where it's -- it feels hard and firm and they move 10 feet off the table when you touch it, that's a pretty good indicator that that's where they're hurting.
Q. (BY MR. MONSOUR) That makes sense to me.
But here's my question: How can you tell by simply touching it and they jump 10 feet off the table and it's hard and firm, how can you tell by doing that that it was probably put in wrong by the doctor that put it in?
A. Well, I've gone in --
MS. DEMING: Object to form.
A. -- cases to remove those areas that are exquisitely tender and thinking that it might have been the mesh that has been implanted and discovered that there's not even any mesh there, that the scarring was

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just -- maybe they'd had previous attempts at removing mesh because of exposure and then the vagina's repaired in that area and it scars down and there's no mesh around there. Or they even have intraperitoneally some adhesion of their colon or small bowel that's stuck to the apex of the vagina right where that point tender spot is.
So you might think it's mesh related because of the temporality of the complaint when the mesh was put in, but then you discover it really isn't mesh at all, it may be something else. Sometimes you can tell -- listen, when the implantation occurs, if everything is -- if -- if there's a -- it may not even be intentional. If there's an overtensioning, especially with -- if there were arms involved with regard to the Prolift device and it wasn't -- and the arms were not all the way to the pelvic side wall but were actually kinked or pulled or twisted or taut right under the vaginal wall more closer to the midline, those are -- those are places where there -- extra scarring can take place, and then you go in and you remove that scar that you palpate and there may be mesh there. But you can't always assume it's always related to the mesh.
Q. (BY MR. MONSOUR) My question was more simple than that. My question is: On you performing your

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exam -- as I understood it, you said, I can go in there and I can feel and I can feel something about how the implant was placed when there's the problem.

What I'm asking you is: How can you as a doctor simply reach inside or examine a woman's vagina and by touching it figure out, hey, that was -- there's something about how that product was placed that is causing that problem? That's what I'm asking.

MS. DEMING: Object to the form, asked and answered.

A. If I can feel the -- if I can actually feel the mesh under my finger when I'm doing the examination in a particular area, then the mesh has been placed superficially.

Q. (BY MR. MONSOUR) Okay. Now, one of the issues that is present in this litigation involves shrinkage of the mesh. Are you familiar with this topic?

A. Yes.

Q. Do you believe that mesh when it is implanted transvaginally can shrink?

A. I don't think so.

Q. Okay. Let me ask it another way. Do you believe that mesh when it is implanted transvaginally, as there is scar tissue ingrowth, that scar tissue ingrowth can cause

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the mesh to shrink or contract?

A. I believe that the -- the collagen that's laid down in between the -- the pores of the mesh that integrate the mesh, they may have some minimally contractual characteristics.

The typical problem with contraction from what I've seen has been when the mesh has -- is overly tightened and there's a -- it encapsulate the scar tissue -- not the scar tissue that grows into the pores of the fabric, but the scar tissue around the outside encapsulates and then that scar contracts, that creates a much bigger problem.

Q. Do you think you would be an appropriate person to try to give expert opinions on shrinkage or contraction?

A. I think so. I mean, from my experience and --

Q. Okay.

A. Uh-huh.

MS. DEMING: Speak up.

A. Okay.

Q. (BY MR. MONSOUR) Let me ask you this: What would be an acceptable amount for a transvaginal mesh implant of shrinkage or contraction so it wouldn't cause a woman problems?

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MS. DEMING: Object to the form.

A. I'm not sure I know exactly -- you're saying what percentage?

Q. (BY MR. MONSOUR) Yes.

A. I don't know the answer to that.

Q. Let me ask -- let me ask it another way. Is there an amount of shrinkage or contraction that if it took place, it would concern you as someone who implants these types of products?

A. The only time it's going to create a clinical problem is if there's -- if maybe the -- one of the things we always did when we put in vaginal Prolift, as an example, was you didn't want to trim any excess vaginal tissue. You wanted to use a suture material that was delayed absorbable, and you didn't want to do anything that would contract or constrict the blood vessels and reduce blood supply.

And if you did -- followed -- and if you did that, you didn't -- if it contracted some, then -- I mean, I don't even know how we would measure that except for the fact that the patient wouldn't be complaining of any particular problem and you could -- you felt pretty comfortable that they were -- you've got good integration of the mesh into the tissue and you did not get an

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encapsulation.

So I don't know -- I do not know how you would -- you know, what's -- what if you -- if you measured something like a -- I don't even know how to measure what the contraction is and if it contracts 10 percent. I -- or whether it contracts 50 percent just on the basis of contraction alone that that's going to be an issue.

Q. I think they look at the size of the mesh implant before it goes in and then I think they try and look at it afterward to determine how much it contracts.

A. You mean --

MS. DEMING: Object to the form.

A. You mean you measure the amount of the size of the mesh you put in and then when you take it out, you measure that size and then you try to come up with an idea that if -- if it was 10 centimeters long and now it's 8 centimeters long, it contracted 2 centimeters?

Q. (BY MR. MONSOUR) Yeah, basically.

A. I've -- well, you have some mesh --

MS. DEMING: Is there a question pending? I'm sorry.

Q. (BY MR. MONSOUR) Yeah, we're trying to get on the same page.

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MS. DEMING: Well, I don't think there's a question pending, so until -- he told you what he thinks it is, you've now asked him about that. I don't think there's a question pending.

A. Okay.

Q. (BY MR. MONSOUR) Here's my question: Would you keep talking about what you were just talking about about that?

MS. DEMING: Object to the form.

Q. (BY MR. MONSOUR) So I can ask my follow-up.

A. Okay. Just ask it and I'll --

Q. Well, my -- I mean, that's -- what you and I were talking about is contraction, correct?

A. Yes.

Q. And you understand that if you put in a piece that's, like you said, 10 centimeters and when they look at it afterwards, after it's been implanted, it's down to 8 centimeters, there are people that have looked at those types of things before and they might conclude, well, that's shrunk 20 percent because it's contracted 2 centimeters, correct?

MS. DEMING: Object to the form.

A. I don't think the word "correct" is the right question. I think the word is do I -- do I think that's

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an adequate way to measure that, and I would say absolutely not.

Q. (BY MR. MONSOUR) Okay.

A. And the -- go ahead.

Q. So you tell me. How would you adequately measure contraction or shrinkage?

A. Well, a lot of times mesh gets trimmed up before it ever gets put in to fit the space. And I never measure -- I never measure, and I don't know any surgeon that actually measures the exact length of what's put in. And then when it's removed, I don't know of any surgeon that measures what's removed and knows that they removed all the mesh that was there.

Q. Assume with me that there are people that have measured before and do measure after, okay? If they are doing that, what amount of contraction would concern you?

MS. DEMING: Object to the form.

A. I don't have any -- I have no experience with that, but I would be very suspect in the mechanism that was used to make that conclusion. I'd have to look at the specific case and see exactly what was talking -- what they were talking about.

Q. (BY MR. MONSOUR) Have you ever looked at any studies that have talked about shrinkage or contraction of

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mesh?

A. Not from a clinical standpoint.

Q. Have you ever looked at any internal Ethicon documents that talked about shrinkage or contraction of mesh?

A. No.

Q. If there were Ethicon documents that indicated that shrinkage or contraction of mesh took place, would you like to see those types of documents?

MS. DEMING: Object to the form.

A. Would I like to see them?

Q. (BY MR. MONSOUR) Yes.

A. I mean, like when, like now?

Q. At any point in time. If you're going to -- if you're going to talk about shrinkage or contraction as an expert, wouldn't you like to know what Ethicon has internally with regard to whether or not their products shrink?

MS. DEMING: Object to the form.

A. Well, it depends on how it is applied clinically. I mean, I'm not sure it would -- that would make any difference in terms of my utilization of the product. I'd have to know a lot more about what the circumstances were and what they were talking about and what the

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specifications are and how it was measured and what it was measured in and what it was measured on and was it measured in a -- on a bench lab or was it measured in a human being or what.

Q. (BY MR. MONSOUR) Well, I think you're quibbling with me on specifics. Just generally --

MS. DEMING: Objection, form.

Q. (BY MR. MONSOUR) -- speaking, if Ethicon has looked at the issue of contraction or shrinkage and has internal documents about it, as an expert that might talk about that, wouldn't you like to see that information?

MS. DEMING: Objection, form.

A. It depends on what the information is.

Q. (BY MR. MONSOUR) What if it's information that talks about how their product shrinks or contracts --

MS. DEMING: Objection, form.

Q. (BY MR. MONSOUR) -- and how much it shrinks or contracts --

MS. DEMING: Objection, form.

Q. (BY MR. MONSOUR) -- and explains exactly how they measure it, wouldn't you like to see that?

A. Only if it --

MS. DEMING: Object to the form.

A. I would like to see it only how it applied from a

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clinical standpoint in humans.
Q. (BY MR. MONSOUR) Okay. Why would you like to see contraction and shrinkage information as to how it applies to humans? Why?
A. Well, if there was really -- if it really made a difference clinically, if it did make a difference clinically, and there was some kind of study that showed that, that in human beings that the -- that -- who had increased mesh problems because of the -- because it was anticipated or thought that it was related to shrinkage, yes. But -- but I don't -- there is no data like that.
Q. How could shrinkage or contraction make a difference clinically?
MS. DEMING: Object to the form.
A. I'm not sure except that if it's -- if it's like -- if the contraction is caused by -- if a contraction is caused from an encapsulation of -- of material such that the material is then blocked, pulled, or tightened, sometimes that increased scarring under the vagina can cause some point tenderness and it might be the case. Again, this has to do with the concept of the mesh becoming encapsulated rather than integrated.
Q. (BY MR. MONSOUR) Okay.
A. And as I said before, there's a lot of different

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reasons that that can happen.
Q. Do you agree with me that if -- if the mesh is implanted in a woman and if the -- it contracts enough, it can potentially cause point tenderness?
MS. DEMING: Object to the form.
A. It can potentially cause point tenderness? I'm not sure. Maybe. I'd have to put a big -- there's a -- because there may be other things that are involved in that particular spot that could cause point tenderness.
Q. (BY MR. MONSOUR) Have you ever looked at studies on slings that have talked about how slings will contract or shrink once they're implanted?
A. No, not -- not that they contract or shrink, but sometimes the position of the patient can make a difference in how much tension there is. We always like to put the -- you know, they're -- it's why they call them TV -- tension-free vaginal tape, because you want to make sure they're applied without tension.
Whether or not once they're implanted and integrated in the tissue, whether or not there's a contraction or it actually shrinks, I'm not quite sure. Part of the problem -- go ahead.
MS. DEMING: No. Finish your answer. If you were finished, that's fine.

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A. I was finished.
Q. (BY MR. MONSOUR) Like you were saying, these devices are supposed to be implanted tension-free, correct?
A. Yes.
Q. If a device is implanted tension-free, truly tension-free, and later on when someone examines the patient notes that there is tension on the product, would that indicate to you that there has been some sort of contraction?
MS. DEMING: Object to the form.
A. No, it would probably indicate that the -- it's maybe not as tension-free as what was described at the beginning.
Q. (BY MR. MONSOUR) So it would be a situation where the doctor might have put it in too tight?
A. Correct.
Q. Have you ever heard of the term "banding"?
A. Yes.
Q. What is that?
A. It typically applies to -- more to slings or at least the arms that were on Prolift. When they're tensioned, if -- you have a -- if you had one here, I could show you.

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But if you -- you know, the TVT and TVT-O tape is a flat piece of material, right?
Q. Right.
A. And it has some stretch. And if you really overstretch it, it -- instead of being flat, it becomes -- the width narrows and it becomes more like a -- like this (indicating).
Q. Let me see if I can describe it and see if you agree with me. As you pull on a flat piece of TVT, whether it's the -- just the mesh, whether it's TVT or TVT-O, if you pull on it, the ends will kind of curl up?
MS. DEMING: Object to the form.
Q. (BY MR. MONSOUR) Is that what you're saying?
A. The form -- yeah, instead of a nice, flat piece of material, it becomes more like that --
Q. Okay.
A. -- a round circular or cord like this.
Q. And what you're doing, just so I can describe for the record, is you're holding the cord to the speakerphone, correct?
A. Yes.
Q. And that's just a standard cord --
A. Yes.
Q. -- right?

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And you think that that phenomenon takes place because when the surgeon was putting the product in, they pulled too tightly on the mesh itself?

A. Yes.

Q. Have you ever heard of a situation where that phenomenon occurs, but the surgeon did not place any excess tension on it?

A. No.

Q. So, in your opinion, when you see something like the banding taking place, that's an issue of operator error, not an issue where the product is poorly designed, correct?

MS. DEMING: Object to the form.

A. Yes.

Q. (BY MR. MONSOUR) And another way that they talk about it is, is they call it periurethral banding?

MS. DEMING: I'm sorry. What did you say?

MR. MONSOUR: Periurethral banding.

MS. DEMING: Object to the form.

A. What do -- you mean that -- that phenomenon --

Q. (BY MR. MONSOUR) Yeah.

A. -- where --

Q. Do you just call it banding or do you call it periurethral banding?

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A. If it's around the urethra, it's periurethral.

Q. Okay.

A. That's the definition of periurethral.

Q. Okay. Have you ever read any studies about banding or anything like that?

A. No.

Q. I want to ask you a hypothetical situation. A doctor places a TVT-O appropriately with no tension. Years later, the patient is examined and a doctor notes banding. Can you explain how something like that could occur if the doctor put in the TVT properly?

MS. DEMING: Object to form.

A. Well, you're making a big assumption that he put it in properly, and you're probably having to base that on the operative report that it was placed.

I don't -- I don't know the answer to that. I know I've put in jillions of them and we haven't seen that. I do have -- I've created a band before.

Q. (BY MR. MONSOUR) How?

A. Well, when we place -- do you want me to tell you how the -- has to do with the technique when you put in a sling?

Q. Sure.

A. I would always use -- I always use a spacer at

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the time we're making our adjustments on the tension. A spacer is the device that you put in between the urethra and the mesh material, and then as you tension it, you tension it up on the spacer so it can't tension up on the base of the urethra.

Q. Okay.

A. Okay. And then -- and the ends of the sling are coming out through the skin, okay --

Q. Okay.

A. -- through needles. You've already looked in the bladder, you know there's no bladder injury, et cetera.

So at this point, you clip the trocars off of the cellophane and the material, and then you have your assistant -- when you finally get it up next to this spacer, your assistant pulls the cellophane off of the ends of the mesh and then you can slip out your spacer and it allows the mesh to lay perfectly flat and tension-free.

Q. Okay.

A. Okay. Now, in a situation where my spacer -- when I was -- when my assistants pulled at the same time the cellophane, the spacer accidentally pulled out and the tension that was placed on the mesh created this.

Q. Okay.

A. Okay. So it was -- I had to -- I had to cut it

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out right then. I mean, I was able to get it out and replace it.

Q. Okay. Fair enough.

And one of the -- what you were talking about -- what you were describing is you put the spacer in between the sling and the urethra and you pull off the -- the sheaths or whatever?

A. Correct, the cellophane sheaths --

Q. Okay.

A. -- that allows the -- the sling material, the mesh, to be in contact with tissue.

Q. Right. And that -- and part of the reason they have the sheaths on there is so they're not stretching the mesh as they're pulling it through the tissue?

MS. DEMING: Objection, form.

A. Well, that's one reason, but the main -- the other reason is you can't -- once the sheath is removed, it's very difficult to move that tissue at all.

Q. (BY MR. MONSOUR) Okay.

A. It gets fixed in place. And so the sheath being smooth, you can make your adjustments that you need to make to put it in the right position.

Q. All right. Now, let me ask you a question. Let's assume that -- let me start -- let me start again.

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In the situation -- the one situation you had where you had the phenomenon of banding, you immediately removed the sling right then and there?

A. Yes.

Q. And you -- did you then put in another sling immediately?

A. Yes.

Q. Okay. So you didn't wait and let that heal and then come back several weeks later. You said, okay, let's take this one out and let's immediately put one back in?

A. Yes.

Q. Okay. If a different doctor did that, not you, but put in the first sling and banding happens and that doctor says, close enough, sews the patient -- closes her up, how soon do you think the patient would start feeling the effects of the banding? Would it be pretty immediately?

MS. DEMING: Object to the form.

A. I don't -- I don't know the answer. Maybe. It's possible it could be pretty immediately. It's possible that it could get encapsulated over the months and then create some problem with pain.

Q. (BY MR. MONSOUR) Because what I think you're explaining to me is as it's pulled and as there's banding

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as you described with the edges kind of curling up, that's as a result of tension, right?

A. Yes.

MS. DEMING: Object to the form.

Q. (BY MR. MONSOUR) And so if it is tensioned too much from the get-go, the patient very likely could feel that very soon after surgery, wouldn't you think?

A. It's possible. It is very possible.

MS. DEMING: Object to the form.

Give me a moment to make my objection before you start answering.

THE WITNESS: Okay. All right.

Q. (BY MR. MONSOUR) Have you ever operated on a woman where she's had the banding where it was implanted by somebody else and you were called in to fix it?

A. At the -- at the time it was implanted?

Q. No, I'm talking about -- I'm talking about one of these situations where -- you know, we talked about your revisions and you said you did -- you've done 12 to 20 revisions and one of them was for yours and you said the other ones other doctors put in?

A. Isn't that amazing?

Yes, I understand what you're saying.

Q. So my question is: Of any of those 12 to 19 that

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you've looked at that -- that were from somebody else, did any of those have the banding phenomenon?

MS. DEMING: Object to the form.

A. I think, yes, maybe one of the slings I removed.

Q. (BY MR. MONSOUR) Okay.

A. And it could have been -- but I don't recall what -- the timing related to the implant. And also with regard to one of the -- an arm of -- an arm of one of the -- of a pro -- not necessarily a Prolift, but one of the arms that was in one of the other Apogee/Perigee design, you know, they were similar.

Q. Okay.

A. And, so, yes. Go ahead.

Q. So my question would be: You believe you have operated twice to repair situations where banding has taken place?

A. Yes, where -- well, yes, there -- in other words, the band -- bands have been removed, pieces of -- like this instead of having a nice, flat piece of material.

Q. And just to be clear for people that are reading this, when you say "pieces like this," you just grabbed the cord --

A. Yes.

Q. -- that goes to the speakerphone?

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A. Yes.

Q. And the situations where that took place, where you found the banding and you operated to fix the banding that had occurred, that was other surgeons had put it in, not you, correct?

A. Yes.

Q. And one of them was a sling, a midurethral sling, and the other one, you believe, was an arm from a POP kit, correct?

A. Yes.

Q. Can you tell me if you can remember the -- those two women -- it was two separate women, I'm assuming; is that fair?

A. Yes.

Q. Do you know whether those two women that you operated on for banding, whether or not their problems took place or they started having problems immediately after the original implants were put in or was it some time later?

A. I don't remember. I don't -- I don't -- I don't think it was within months of the -- I think it was longer than months after the original implant.

Q. So there would have been time for tissue integration into the mesh?

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A. Well, I think one of the problems with banding, when it becomes this type of rope, you can't get integration.
Q. Okay.
A. That's part of the problem.
Q. Okay.
A. But I -- go ahead.
MS. DEMING: Finish your answer.
A. I'm finished. I finished. I was going to -- I'm through.
Q. (BY MR. MONSOUR) I'll usually let you talk. If you want to say something, I'll let you do it. I'm usually not one of the ones that yells at people, "that's not my question."
MS. DEMING: Are there people that do that?
MR. MONSOUR: Yeah, you think?
MS. KROTTINGER: Never.
Q. (BY MR. MONSOUR) I think you've acknowledged this already, but I just want to clarify it. Or you've at least touched on it.
There is a term that you've used, and I've heard other people use, palpable mesh. That means you can feel the mesh once it's been implanted, correctly -- correct?

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A. Are you talking about palpating or feeling the -- the mesh fabric underneath the tissue?
Q. Yes.
A. Yes.
Q. In a situation where there has been palpable -- you can feel palpable mesh, if you were -- if a woman came to you and was having complaints about her implant and you examined her and you found palpable mesh, would it be your opinion that the mesh was implanted superficially?
A. Yes. Or -- or it may have been implanted in the right space and the vagina became thinner.
Q. Okay.
A. And -- and if the vagina became -- because of atrophy and age so that the -- so that the mesh that's sitting on top was then -- it was easier to palpate because the vagina was very thin.
Q. Fair enough.
If somebody came to you and they had -- and you could feel palpable mesh and you thought -- you thought their vaginal tissue was just thinning, what would you do to help them with that condition?
A. Well, it would depend on what they were complaining about.
Q. Okay.

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A. Most of the time in that situation when you palpate, you can palpate mesh, it's in a patient who's asymptomatic.
Q. Okay.
A. In other words, it's implanted maybe when they were younger and it was in the right place, and then they've gotten older and they didn't use any hormone replacement and the vagina got thinner and you can feel it on the examination, but it doesn't hurt and they're not complaining of anything.
Q. If they had no complaints, would you just let it go or would you give them an estrogen cream to try and help thicken up the vaginal walls?
A. Well, that --
MS. DEMING: Object to the form.
A. That depends on a lot of things. If they're complaining of dryness and have other vaginal complaints, then, yes, we may use an estrogen cream or some type of something. If they were -- if they could take estrogen. Some patients -- you know, maybe they're breast cancer patients that can't use estrogen. So, anyway, there's -- there's some other options for them, but it just depends on the individual circumstances.
Q. (BY MR. MONSOUR) Okay. I guess I'll look at my

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outline.
MS. DEMING: You're like me. You do -- you do a nice outline and then you never look at it except to check things off to make sure you covered it.
We've been going about another hour.
MR. MONSOUR: Why don't we take a lunch break.
(Lunch recess.)
Q. (BY MR. MONSOUR) All right. We are back after a lunch break. Dr. Shoemaker, are you ready to continue?
A. Yes.
Q. Okay.
(Exhibit 3 marked.)
Q. (BY MR. MONSOUR) Let me hand you what I've marked as Exhibit 3.
A. Okay.
Q. And is that a complete -- is that your complete billing for your work as an expert for Ethicon in this litigation except for what might have been done in the past couple of days to get you ready for your deposition?
A. They're -- I believe this is the -- let me just go back.
Yeah, this -- this invoice covers November to December. There's a -- Butler & Snow is another law

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firm that originally contacted me --
Q. Right.
A. -- about a year ago. And, quite frankly, I can't remember whether or not there was any invoices prior to starting counting hours in November.
MS. DEMING: I will represent to you that I checked with Butler Snow and these are the only three invoices that they have.
MR. MONSOUR: Okay.
THE WITNESS: Okay.
Q. (BY MR. MONSOUR) All right.
MS. DEMING: But as you can see, he's doing them in, like, monthly or whatever, so -- any April time, he has not billed us.
MR. MONSOUR: Right, that's what I was -- today's April the 5th?
MS. DEMING: Uh-huh.
Q. (BY MR. MONSOUR) So Exhibit 3 is your time through March 31 --
A. Right.
Q. -- of 2016?
A. Correct.
Q. Okay. And if I add it up, it looks to me like it's about 40, 41,000, ballpark. Does that sound about

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right?
A. Yes, sir.
Q. Okay.
A. Yeah.
Q. Now, for the work that was done -- do you know when you completed these reports, your two reports in this case?
A. The end of February, I think.
Q. What's that?
A. The end of February.
Q. End of February.
A. I think that's right. Maybe middle of February. Somewhere in the month of February.
Q. Okay. So your reports -- well, you sent a bill on February 25th of 2016. So did you probably send the bill around the time you were wrapping up your reports?
A. Probably.
Q. Okay. So up through the time of your reports, you've got 10 hours on the first bill, 22 on the second, and 29.5 on the third bill. Does that sound about right?
A. Yes.
Q. Okay. Your reports -- did you write them?
A. Yes.
Q. Did you write them all by yourself?

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A. Yes. I mean --
MS. DEMING: Object to the form.
A. I wrote all the words, somebody else typed it, but, yeah.
Q. (BY MR. MONSOUR) Did you dictate it or how did it go?
A. I usually wrote or I put it in a Word -- you know, on the computer, tried to type something up, or I handwrote it --
Q. Okay.
A. -- which is a little daunting.
Q. Okay. All right. I want to switch topics. I want to ask you about the topic of degradation. Your report mentions that a little bit.
MS. DEMING: Let me stop you for a minute. For the record, we extended the deadline on a couple of the cases that he's been doing because he had to do an IME or two after the report deadline. So I just wanted to make you clear that there was other stuff being done after this general report, for example, was completed.
MR. MONSOUR: But that would be case-specific stuff?
MS. DEMING: It is, absolutely.
MR. MONSOUR: Okay, yeah, that's okay. I

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know that --
MS. DEMING: I just wanted to be complete.
MR. MONSOUR: I know there's some give and take on specific cases, so I think -- I've done that and y'all have done that with me on a few, so --
MS. DEMING: Sure.
MR. MONSOUR: -- that's understand --
Q. (BY MR. MONSOUR) But let me just clarify this. As far as your work on general theories of liability and the products themselves, that's all encompassed in the billing that is in Exhibit 3?
A. Yes.
Q. And, actually, if I look at Exhibit 3, this also does include some case-specific work you've done. For instance, on the third page it mentions -- looks like IMEs for Dimock and Morrow.
A. Right.
Q. So now that we've got that clear, degradation, are you familiar with that subject matter with regard to the transvaginal mesh products?
A. I've just heard that it's been -- it's been mentioned as a potential complication with the material.
Q. Okay. Have you ever done any studies on -- have you ever done any research on the topic of polypropylene

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mesh degradation?
A. I haven't -- I haven't -- only to the extent that I've seen it written about with regard to this litigation.
Q. And -- and. Okay. So you've done no personal research or scientific studies on the topic of degradation?
A. On polypropylene?
Q. Yes.
A. No, I have not.
Q. Would you consider yourself an expert in the field of polypropylene degradation?
A. In what respect?
Q. With regard to polypropylene transvaginal mesh products.
A. Only to the extent that they're in -- whatever clinical application might be appropriate.
Q. Okay. Well, let me ask this question: Do you know whether or not polypropylene mesh, once it's implanted in the vaginal area, if it degrades at all; do you know?
A. I have -- I certainly have never seen that -- have I had an experience with that? I've never seen that happen. I've never read any of the -- any of the studies related to -- clinical studies comparing polypropylene to

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other native tissue repairs. I've never seen any comments on any of those papers related to some issue that the -- that the mesh may be degrading or disappearing or going away. I mean -- you know, we've -- I can't imagine.
I mean, as far as I know, all the polypropylene sutures that we've used for, you know, decades hasn't gone away. So I don't -- I -- I've never seen that happen, nor have I ever read about that happening. I've just seen it in some discussions related to this litigation.
Q. Are you aware that there are some articles that are published about polypropylene degradation that are out in the scientific community?
A. You mean unrelated to the clinical aspect of pelvic organ prolapse?
Q. Well, I'm just talking about where they actually look at -- where they actually look at the polypropylene and determine whether or not it degraded once it was implanted.
A. I've -- I -- I have not seen that specifically. Whether you're talking about like a -- a laboratory study where they've seen the material go away or disappear, I've never seen that. I certainly have never seen it in any kind of application related to the surgical procedures

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that we do.
Q. Do you --
A. And I've -- and I've gone back in on surgical cases in which Prolene has been there -- around for 20 plus years and it's still there.
Q. Have you ever looked at it microscopically?
A. No.
Q. And I think you'll agree with this. Sometimes a microscope will give you a better view of something that's small like mesh than your naked eye would, correct?
A. Oh, in what -- in what application? Because if it doesn't make any -- I mean, if it's not a clinical issue, what difference would it make whether microscopically I could see that it had decreased in diameter or whatever?
Q. Well, that's my question, though. My question is more: Have you ever looked at it microscopically to determine --
A. No.
Q. -- whether or not that's taken place?
A. No, I have not.
Q. Okay. And you've never read any studies about whether or not degradation takes place in polypropylene transvaginal mesh implants once it's -- once it's

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implanted, true?
A. No. And I've never -- and I've never seen -- no. And I never thought that it mattered, because I've seen polypropylene, you know, numbers of years later and it was -- it looked the same.
Q. With regard to your expert reports, there's a couple of things. You've got -- there's a reliance list of things that you relied upon. Are you familiar with --
A. Yes.
Q. -- that document?
Who put together the documents on your reliance list?
A. You mean put the -- this together?
Q. Yes.
MS. DEMING: The list together.
A. Yes. They put -- we put the list together. We commented about it with the -- with Kay, and then her staff actually grasped the documents or printed them and put them in those folders.
Q. (BY MR. MONSOUR) Okay. Well, I guess my question, though, is simpler than that. On your reliance list, there's a list of, like, internal Ethicon documents that you've looked at?
A. Internal Ethicon documents like what?

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Q. They're Bates stamped. Have you -- did you look at any internal Ethicon documents?
A. Give me an example and I'll tell you.
MS. DEMING: I can state for the record the list was -- it's a materials list that Butler Snow keeps up with anything that has been sent to him.
MR. MONSOUR: Okay.
MS. DEMING: And then he looked at it to see if he had add -- you know, if there were things that needed to be added to it --
MR. MONSOUR: Okay.
MS. DEMING: -- that he had looked at independently.
MR. MONSOUR: Right.
MS. DEMING: So it's a list, really, that provides, you know, an accounting, if you will, of everything that he's had and then he could choose to look at whatever he wanted to.
(Exhibit 4 marked.)
Q. (BY MR. MONSOUR) So I've marked as Exhibit 4 your reliance list, correct?
A. Okay.
Q. And who -- who determined what you relied upon, I guess, is my question?

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A. Well, a lot of it I relied -- you mean in terms of record -- clinical trials and papers that have been written?
Q. Yes.
A. I relied on some of that. Some of that they sent to me. I sent some stuff to them they hadn't seen, some --
Q. Well, like -- let me ask you this question: There's a memo from Dan Smith to David Robinson, Re: Elongation characteristics of laser cut Prolene mesh for TVT.
How was it determined that you needed that document? Did you request it, did somebody send it to you and, say, hey, you might want to read this?
A. I may have requested that, because there was some -- something I read about -- there was an issue about laser cut versus a mechanical cut. So I might have asked them if they had any data or any papers about that and they may have sent that to me.
Q. Okay. But I guess they were the ones that were determining what was sent to you?
A. Well, if I -- yeah, if I -- well, in some cases, that's correct; in some cases, it was not.
Q. Okay. You might mention a subject and say, I would like some information on this subject and then they would then determine what was sent to you on that subject. Is that a fair summary?

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A. Often that -- often that would happen and sometimes I would have the information myself.
Q. Okay.
MS. DEMING: That is Exhibit 3, did you say?
MR. MONSOUR: Yeah, that's exhibit -- Exhibit 4. I'm sorry.
Q. (BY MR. MONSOUR) And then there's a bunch of studies in here on your reliance list. Do you see those?
MS. DEMING: You mean the published articles?
MR. MONSOUR: Yeah.
MS. DEMING: Okay.
A. Yes.
Q. (BY MR. MONSOUR) How -- how did the list of published articles come up? Were they provided to you or did you come up with them?
A. Some of them were provided to me if I was on a particular subject, and then some I already had or I had reviewed. I reviewed articles periodically and in -- in -- but since all this -- since the litigation started, you know, everything's been focused on this, you know,

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pelvic floor and pelvic floor mesh and slings, et cetera. So --
MS. DEMING: Speak up.
A. So, anyway . . .
MS. DEMING: Did our people ever dial back in?
MR. MONSOUR: I don't know. That's not --
MS. DEMING: Not my problem.
MR. MONSOUR: -- my problem. Okay.
Q. (BY MR. MONSOUR) Could you tell me which subjects you requested additional -- well, let -- let me ask it this way. Let me start this.
Your report or your reliance list has two sections on it, basically. One is medical literature and the second one is documents, correct?
MS. DEMING: And for the record, there -- with each report, for example, in a case-specific report, there will be added material that was specific to the case.
MR. MONSOUR: Okay.
A. Some of these --
MS. DEMING: Like, medical records and things like that.
A. And I think there may be some duplication if --

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anyway.
Q. (BY MR. MONSOUR) So here's my question -- am I right, though? Does it -- does your reliance list basically have two sections, one that's medical records, the other one looks like Ethicon documents?
MS. DEMING: Object to the form.
A. I haven't seen this put together in these pages, so . . .
Q. (BY MR. MONSOUR) That's why I'm letting you look at it.
MS. DEMING: He's referring to this area back here.
Q. (BY MR. MONSOUR) It's broken down at the top. See, if you look here, this -- your medical literature seems to stop on this page and then you flip over and it says, "Document Description" --
A. I gotcha.
Q. -- and then it's got the Bates numbers.
MS. DEMING: And it's got Bates numbers and individual things.
A. I see.
Q. (BY MR. MONSOUR) Does that appear to be how the --
A. Yeah.

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Q. -- the list was broken down?
A. Yeah. And this may be stuff that they sent to me. It doesn't necessarily mean -- and I perused some of it, but some of it I may not have complete --
Q. Okay. And that's what I was going to get at. Some of it they sent to you probably at -- as their choice just to say, here, in case you want this, and then others -- topics you might have requested --
A. Correct.
Q. -- literature or documents on, correct?
A. Yes. Uh-huh.
Q. Could you tell me which topics -- so we don't have to go through each document, which topics did you request that they send you information on?
A. Well, any topic that -- where I -- it was mentioned as a complaint with regard to some litigation, that was -- that would all be -- would be one. And, for instance, I made a list here. In fact, if you want -- you might want to copy it. These are particular articles that I've couched that apply to things like voiding problems after -- these are all postsurgical --
THE REPORTER: Postsurgical what? Speak up.
THE WITNESS: I'm sorry. What now?
THE REPORTER: Postsurgical and then I

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couldn't hear you.
A. These are postsurgical issues that are commonly associated with some of the complaints that people have in the litigation. So failure of recurrence or failure of their prolapse, exposure and erosion, chronic pelvic pain, dyspareunia, voiding problems, and quality of life.
Q. (BY MR. MONSOUR) Can I see those?
A. Yeah.
Q. And so on these handwritten pages that you've just handed me, this is your handwriting on these, correct?
A. Yes.
Q. And so there -- it looks like there's -- you're citing, it looks like, some medical articles, correct?
A. Yes.
Q. And is that research that you did on your own?
A. Yes.
Q. Okay.
MR. MONSOUR: I'm going to mark this as Exhibit 5.
(Exhibit 5 marked.)
Q. (BY MR. MONSOUR) Okay. I'll mark this as Exhibit 5.
So Exhibit 5 is basically a list of medical

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articles that you came up on various topics that you are aware were complaints or issues -- medical complaints or issues that have been brought up in the litigation?
A. Correct.
Q. Okay.
A. Yes. And in my -- and in my own experience, I've had patients that came in that had these kind of problems as well.
Q. Okay. And then if we go back to Exhibit 4, which is your list, it appears that at least a significant number of these documents that are attached would have been documents that were sent to you by Ethicon's counsel saying, here, you might want to read this?
A. A lot of that, yes.
Q. Okay. And then are there any -- on the -- on the list -- not on medical journals, because I think this kind of covers that. But as far as documents, Ethicon documents, can you tell me specifically the topics where you would have contacted their lawyers and said, hey, I would like to see the documents or some documents about issue X? Can you tell me what issues those would have been?
MS. DEMING: If he did. Object to the form.
A. I don't think I did.

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Q. (BY MR. MONSOUR) You didn't?
A. I don't think I ever asked specifically for any particular document related to anything.
Q. Okay. All right. So all of the documents that are listed on Exhibit 4 were those that were hand-selected by Ethicon's lawyers to send to you, the documents, not the --
A. Yes.
Q. -- scientific articles, correct?
A. Yes, I would say that.
Q. Okay. Did you read them?
A. Probably not.
Q. Okay. All right.
MS. DEMING: That's going to cut things down.
Q. (BY MR. MONSOUR) That's why I ask questions that way. Makes it a lot simpler.
Let's go back to the topic of degradation. Do you know what reactive oxidative species are?
A. You mean like species like germs, bacteria?
Q. Yes.
A. Do I know what they --
Q. Do you know what they are?
A. No.

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Q. Okay. Do you -- do you know what peroxides are?
A. Only to the extent I've read that in some of the reports from some of the experts on the plaintiffs' side.
Q. Okay.
A. I've read those words.
Q. Okay. But you're unfamiliar with those topics?
A. Correct.
Q. Okay.
A. Only -- yes, to the extent that I -- in my -- I mean, I have not had any clinical significant experience that may be related to that.
Q. Okay. Do you -- do you know if peroxides are present in a woman's vagina?
A. Peroxides?
Q. Yes.
A. She may have put it there.
Q. Okay.
A. Are you talking about if they just occur naturally there?
Q. Yes, if they occur naturally.
A. I don't know.
Q. All right. Let me see. You have given a deposition before today, correct?
A. Not related to anything that has to do with this subject.

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Q. Okay. All right. This is your first transvaginal mesh depo ever?
A. Ever.
Q. Okay. All right. How long have you -- how long have you worked -- or excuse me.
When were you retained by Ethicon to be an expert for them in this litigation?
A. I was -- it was discussed -- probably it's been a year ago, maybe eight -- the late spring of last year.
Q. So 2015?
A. Yeah.
Q. Okay. And -- but it seems like your work didn't start until very, very recently?
A. Well, the end of 2015 because --
Q. End of 2015?
A. Yeah.
Q. And then this year some?
A. Yeah.
Q. What prompted you to be an expert for Ethicon? Why did you do that?
A. You mean as a -- in this litigation, you mean?
Q. Yes, sir.
A. Well, I've had a relationship with Ethicon for a number of years as a -- as a preceptor/instructor going back to the late '80s.
Q. And could you describe your relationship with Ethicon, what you've done with them or for them over the years?
A. Yeah, I was -- I was a preceptor for them in the late '80s, their Ethicon endosurgery, which was their laparoscopic division, about the time -- in fact, I was involved -- one of the -- with their -- after they developed their training center in Cincinnati for products related to laparoscopic surgery. And that was in the late '80s.
And -- and so we were designing at that time trocars and different types of substitutes for suture materials, stapling devices and that kind of thing that I was involved with. So I would teach -- and physicians would come down and -- I was a very -- had been an advanced laparoscopic surgeon. And so we did surgical training, and I was involved in some of the surgical training related to everything from laparoscopic hysterectomy to laparoscopic gallbladder surgery.
Q. Okay. As far as transvaginal mesh products, both POP and SUI, when did your relationship with Ethicon begin?

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A. Well, they began a division, Women's Health and Urology, in the early 2000s. I'd already -- I had already started doing TVT slings that -- when -- when that product was actually produced by a company called Gynemesh. And I think Ethicon bought Gynemesh and so -- and so it became their product.

And so they were -- so I was asked at that time to look at the product and -- and use it, and then after a while, they were asking me to preceptor doctors coming down and operating with them. So I began the slings in the early 2000s and then with Prolift when it was introduced in probably 2005 or '6, something like that.

Q. And as a preceptor, that's -- a preceptor, that's a situation where you're a doctor in an area that knows how to do a certain procedure or use a certain device, other doctors that might want to learn how to use that procedure come see you and learn firsthand from you, correct?

A. Yes.

Q. And the company pays you to teach them how to use their product?

A. Yes. There's kind of a sequence that I would go through in terms of that educational process for other

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doctors, but, anyway . . .

Q. Tell me the sequence.

A. The -- what I like to do is have the docs come -- well, oftentimes, we would end up meeting at a cadaver lab that the company would provide to introduce something new and to -- from a training standpoint, and then they would allow -- then after that -- and I was involved in some of those cadaver labs as well.

And then if the docs wanted more hands-on type training, then they would come to Corpus Christi and we would have some cases that I -- my cases. And so they would be observers. And then I would talk to them a little bit about what the procedure was, et cetera, and how we -- how we utilized this particular product.

And then often -- and there was a questionnaire that would have to be printed up, and then I would have to put my signature of approval, whether I thought this doc was adequately trained or not. But before I would do that, oftentimes, I would go to where his hospital was. This was at a time when you could actually get hospital privileges a lot easier than you can today.

But I would get privileges at his hospital and actually assist him in some of his or her first cases,

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and then after that experience, then I felt comfortable in deeming them qualified for doing a certain type of procedure.

Q. Okay. When they were -- when they would first come to see you --

A. Uh-huh.

Q. -- and on -- working on your patients, would they scrub in?

A. Yes.

Q. Okay. And actually help with the procedure?

A. No, not -- well, that varied. That wasn't always the case. Our hospital was pretty lenient in allow -- and let me kind of control that. I mean, they weren't there knowing that they were going to be able to be hands-on, but I would often have them scrub in just so that -- because in vaginal surgery, if you're not scrubbed in, you can't see.

Q. Okay.

A. It's just technically impossible to see the anatomy and see what's going on if you have to be away from the operative field.

Q. Just -- just from the physical construction of where you're operating?

A. That's correct.

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Q. Okay.

A. In laparoscopic surgery where everything's on a monitor, that's totally different. You know, everybody in the room can look at a monitor and kind of see what the procedure is.

Q. Have you ever voiced any criticisms to Ethicon about any of their TVT products?

A. No.

Q. Have you ever voiced any criticisms to Ethicon about any of their pelvic organ prolapse products?

A. Yes, yeah, the only one was -- would -- I would say is Prosima. I was a key opinion leader when Prosima was introduced, and that came through their division of Women's Health and Urology.

And so they would have meetings, key opinion leader meetings, and we would discuss different things. And in the Prosima case, there might be 10 or 15 docs that were from around the country that would get together for a day or two and, you know, talk to them about our -- give them some input about what our opinion was about certain things.

Q. What were your criticisms of Prosima?

A. The biggest one was that I didn't like the -- the little device that they provided in the kit to put -- to

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place the arms of the Prosima. It was a little awkward and difficult to use.

So, you know, you'd have 15 people in the room from all over the country and everybody would just start talking about different things and people would have different opinions. And so it gave the company an opportunity to hear some issues from these people that were using the product a lot and it gave us an opportunity to learn maybe from somebody in Nebraska or something, you know, say, oh, yeah, I had that problem, too. So it was a good deal for all of us.

Q. Okay. Have you ever had -- you've worked with various transvaginal mesh products made by other manufacturers, true?

A. Very minimal experience.

Q. Okay.

A. But they would often call me and want to introduce something, but it was -- you know, it's kind of like, you know, you get into using a certain thing that you like and, you know, you -- you -- because you do a lot of certain types of cases, you're sort of a target for a lot of people that want you to evaluate things.

But it was very -- so occasionally I would use, maybe once or twice, something that was not an

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Ethicon product, but I was so happy with the Ethicon products and the way they were working that it was -- I never had -- I never saw any other product that was -- that made me say, well, you know, I really need to start using something different because it's better for my patient.

Q. Basically because -- as we were discussing earlier in the depo, you've probably put in well over a thousand transvaginal mesh products. That can make you a target to salespeople from competitor products --

A. Yes.

Q. -- that want you to start using their product?

A. Yes, or -- yes, yes, that's correct.

Q. They probably call you every week to try and get you to switch?

MS. DEMING: Object to form.

A. Over -- over a particular time period, yes, that was correct.

Q. (BY MR. MONSOUR) Okay. Do you still -- other than your expert work, do you still have a relationship with Ethicon where you're a preceptor for them on anything?

A. No.

Q. Is the -- is the da Vinci robot, do you teach --

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are you a preceptor for da Vinci?

A. I am.

Q. Okay. Are you a preceptor for any other companies?

A. This company, ACell, that makes the MatriStem product, the biologic, I do preceptorship with them.

Q. Okay. As far as your background, I know you've worked on this litigation. Have you ever done any other expert work in litigation before?

A. You know, yes, before Prop 12 in Texas where there was a lot more malpractice litigation going on, I was often called on to review cases, malpractice cases.

Q. For which side, plaintiff or defense?

A. Both. Probably more defense than plaintiff's side, but I did -- I -- I did review cases for plaintiffs' lawyers and sometimes I'd tell them that they did not want me for a particular case, too.

Q. I've heard that story before.

Which plaintiffs' lawyers did you work with?

A. You know what, the last -- I couldn't -- I couldn't tell you. The last case was probably in the mid to early '80s, you know, with -- the only one I remember vividly was -- it was -- the plaintiffs were -- the plaintiff was in Oklahoma. It was -- it was a -- it was a

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medical malpractice case. It was an obstetrical complication case. And I was a plaintiff's expert and -- and -- yeah, but both -- I guess both the defense -- yeah, the -- the doctor was from Oklahoma, so I guess the defense lawyers were from Oklahoma City, yeah.

Q. Did you do a lot of brain damage baby cases, expert work?

A. Not really, not -- I mean, sometimes I'd review records typically on the defense side.

This plaintiff's particular case that I remember vividly was a maternal death case.

Q. Okay. Have you ever testified live at trial?

A. I have.

Q. When was that?

A. Probably that -- I'm going to say the mid -- mid to late '90s. It was a case out of Kingsville, Texas, which is a community close here -- close to here.

Q. Yeah.

A. And that was -- that was a defense case. And it was a -- it was an obstetrically related malpractice case. And you may know Darrell Barger.

Q. Yeah.

A. Darrell and I are very close friends. And he was the defense lawyer in that case.

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Q. Okay. Have you ever worked to -- have you ever worked with a company to help get a product through the FDA 510(k) process?
A. I have not.
Q. Do you have any specific knowledge about the 510(k) process?
A. No.
Q. Have you ever worked with a company getting a product approved through the PMA process?
A. I never -- no, I haven't. Is that the device process?
Q. Yes.
A. I've never worked with a company to try to get a product through. I'm fairly familiar with some of that, somewhat related to this, with regard to the FDA.
Q. Okay. Would you -- I guess what I'm getting at is would you consider yourself an expert on the 510(k) process or the PMA process?
A. No.
Q. Okay. One of the things that you talk about in your expert report are the instructions for use that accompany a product?
A. Uh-huh.
Q. Why -- what is your understanding of the reason

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why they have instructions for use?
A. Well, I think they're just sort of basic instructions that apply specific -- that apply to how -- what may be unique about the device in terms of how it relates to a particular surgical procedure.
Q. Do you think that if the company is aware of adverse -- adverse reactions or problems with their product, it should be disclosed to doctors in the IFU?
A. Well, if it's a -- if it's related to something from a clinical standpoint that's important to -- yeah, then I think it may be.
Q. Okay. But in -- in all fairness, if the company knows about certain issues with regards to its products, you believe that they should share that information with doctors so the doctors can perform an appropriate risk balance evaluation?
MS. DEMING: Object to the form.
A. I think it depends on the -- what the application is. I mean, you know, if it's -- the handle's too heavy and it may hurt your foot if it hits the floor, I don't care about knowing that kind of thing, I mean. But -- so -- I mean, you can get to a point where you can add hundreds and hundreds of possible complication and things and then it becomes -- it becomes meaningless. So I

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haven't really relied on the instructions for use in order to make what you call the risk and benefit ratio to determine that.
Q. (BY MR. MONSOUR) One of the things as a preceptor --
A. Yeah.
Q. -- you've been through some of their training programs --
A. Yeah.
Q. -- correct?
They do go through the instructions for use at those?
A. Yeah.
Q. And all -- all aspects of the instructions for use?
A. Yeah.
Q. And, I mean, at least that's what their corporate people are telling me.
A. Oh, yeah.
Q. Okay.
A. So, then -- what I mean is when I'm in a preceptor situation or a training situation, certainly, I review -- say, look, here's -- you know, this is some things you need to be aware of when you handle this

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instrument and you handle this device. But it's not the company -- I guess the point I'm making is there's a lot of things that happen to patients that's -- that are adverse or a complication that may be related to the surgery and not so much the product. And so it's not -- I don't think it's the company's responsibility to try to teach doctors how to operate.
And let me tell you, what I -- when I described to you sort of my critique on how I handle doctor instructions and them coming and observing, discussing, and then going and operating with them, I learn a lot about the surgeon. And not every surgeon is equal.
Q. I'd say that's a pretty reasonable statement.
With the understanding that not every surgeon is equal, is it probably also fair to say that not every surgeon stays abreast of current medical literature?
MS. DEMING: Object to form.
Q. (BY MR. MONSOUR) Is that a fair statement?
MS. DEMING: Object to the form.
A. I -- well, I would probably -- I'd have to probably say yes.
Q. (BY MR. MONSOUR) Okay.
A. Knowing that there might be surgeons out there

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that don't stay as abreast of medicine as others, one way that a company can ensure that they get up-to-date information on the adverse issues with their product is to include that in the instructions for use --

MS. DEMING: Object to the form.

Q. (BY MR. MONSOUR) -- true?

A. Well, it depends on what the instructions are. I mean, if you're going to put in the instructions for use that you might injure a blood vessel when you perform the surgery, well --

Q. Duh.

A. I mean, right.

Q. Right.

A. I mean, in other words, you can add so many things.

Q. What you think --

MS. DEMING: Let him finish.

Were you finished?

THE WITNESS: Yes, I was finished.

MS. DEMING: Okay.

Q. (BY MR. MONSOUR) Let me -- let me see if I can -- in the instructions for use, you believe a company is not obligated to teach the doctor how to practice medicine or to teach them how to operate, true?

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A. True.

Q. However, do you believe that if there are issues unique to the product, that that information should be shared with the physicians?

MS. DEMING: Object to the form.

A. If that -- if that -- if that information about the product is -- has clinical significance --

Q. (BY MR. MONSOUR) Okay.

A. -- then -- then -- then, yes, if it has clinical significance in the form of its uniqueness to that particular product.

Q. Okay. Fair enough.

A. And I'm happy to look at an individual bit of information and discuss that with you if you want. But just overall, that's my overall opinion.

Q. Okay. But it involves -- what you're saying is, is the company needs to include in the instructions for use issues that are unique to the product and that have clinical significance?

MS. DEMING: Object to the form.

A. I would say if they have -- yes, if they have clinical significance and -- and the clinical significance is going to -- makes a difference in how the product is used, yes.

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Q. (BY MR. MONSOUR) Okay. Do you consider yourself an expert in -- in instructions for use as far as what is required to be in them?

A. As long as it applies to -- it has clinical significance, and as long as it applies to, you know, what I'm -- what I do, you know, clinically and as long as it takes a -- as long as it -- as long as it's relevant to the realm of surgery that I'm doing.

Q. Okay. Let me ask it this way: Is it a fair statement to say that as a surgeon, you use a lot of different medical devices?

A. Yes.

Q. Is it fair to say that as a surgeon, you have read a lot of instructions for use for medical devices over the years?

A. Yes.

Q. Would you say your experience -- or your expertise is derived from your working with and using so many instructions for use over the years?

A. No.

Q. Okay. Explain it --

A. No.

Q. -- to me, then.

A. No, I mean, I read the instructions for use and I

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see what the specific things are that are -- but, you know, my -- my -- the criteria I use on whether I'm going to continue to use the product or not really has very little to do with what the -- the IFUs as presented.

I mean, there's a lot more other things that go into the use of that product that makes a decision -- where I make a decision about whether I'm going to continue to use it far beyond what -- the instructions for use.

Q. I asked an inartful question. Let me -- let me -- let me -- let me -- let me reask the question.

Your knowledge on instructions for use is based on the fact that as a surgeon, over the years, you've read and utilized a lot of instructions for use?

A. I've read and utilized instructions for use -- just read it and then how much I've relied on it in terms of whether I continue to use the product or not may not be exactly the same. I mean --

Q. I guess what I'm getting at, though, is, is that would -- your knowledge based on instructions for use is based upon your experience as a surgeon, not with working with the company to help draft them or working with the FDA to see that requirements are met. Your experience with instructions for use is -- is -- is that --

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A. Clinical.
Q. -- your experience clinically --
A. Yes.
Q. -- correct?
A. Yes.
MS. DEMING: Object to the form.
Q. (BY MR. MONSOUR) Have you ever participated in designing a clinical study?
A. I've had a couple of papers published, but they -- they were not really -- yeah, there was one that was a clinical study back when I was a resident.
Q. Okay.
A. It was an obstetrically related study when I was at Parkland.
Q. Would you consider yourself an expert in designing clinical studies?
A. Only to the extent that I've done some myself, but I can read studies and make a decision about whether they're -- how -- how appropriate they are and how credible they are.
Q. Okay.
MS. DEMING: Off the record.
Q. (BY MR. MONSOUR) Have you -- have you ever designed a medical device?

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A. No, I have not.
Q. Would you consider yourself an expert on the design of medical devices?
A. Again, only to the extent that -- how it's applied in my surgical hands and whether it -- you know, how functional it is from that perspective.
Q. So your design expertise would basically be more of a -- it's already designed and you use it and you can say, yeah, it seems to work or, no, it doesn't?
A. Yeah, exactly.
Q. Okay. It would be from a user's perspective, not from a designer's perspective?
A. Correct.
Q. Okay. Do you know why they pulled the Prolift from the market?
MS. DEMING: Object to the form.
A. The only thing I was told was that they were -- there was a -- after the FDA in 2011 basically said if you're going to market these vaginal mesh devices, you're going to have to come do -- produce some 522 study -- the 522 study thing, and this is what you're going to have to do. And I think at that -- didn't they reclassify it as a Level 3 product rather than a -- or that just recently happened.

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Q. (BY MR. MONSOUR) Yes.
A. But, anyway -- so I think the company decided that instead of going through with the 522 study, that they -- it was -- the cost-benefit ratio to them was not there from a business standpoint.
Q. And you heard that from the company?
A. Yeah.
Q. Did that come from your sales rep with the company or somebody higher up the food chain?
A. No, I think -- I can't remember his name anymore, but there was somebody -- I think -- it may have been in the -- December of 2011, I was at a conference in -- a PAGS conference, pelvic anatomy and GYN surgery conference, that was always held in December.
And at that meeting, the -- I'm trying to think of -- it was the guy that was the director of -- for Women's Health and Urology, that division of Ethicon, indicated at that time to me that they were going to quit making vaginal devices -- I mean, the vaginal products, so -- but they were still going to make the slings, that was not an issue, because that -- in the -- in the FDA hearing in -- in August of 2011, the slings in -- that the transobturator -- the traditional transobturator and transvaginal slings were not required to do additional

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studies and they were allowed to stay on the market. The only sling that was required to participate in the 522 study were the mini slings, the single-incision slings.
And then from the medical device -- from the vaginal meshes that were being made, I think the company -- Boston and AMS, Ethicon, Bard, they were going to have to produce -- redo their -- or redo the -- the big criticism was that there was not a control group with their initial clinical trials. So they said you're going to need to do -- that's what the 522 study was designed to do.
So -- so, anyway, Ethicon at that point decided from a business standpoint, that they didn't want to participate because of the -- I know a little bit about that, because ACell, the company that makes this biologic graft that I currently use, is participating in the 522 studies. And it took until -- let me think about this. It took -- those studies just began a year ago. So from 2011 until 2015, it took four years to put a study design together where the urologic societies and ACOG and everybody agreed to the design of the study. And then it's going to take probably five more years before they actually have data.
Q. Have you ever worked with any of the mini slings?

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A. I've put in maybe one or two.
Q. Did -- what did you think of the mini slings?
A. Well, the idea was intriguing, because I think when they originally came out, the concept was that it might be something that would be simple enough to do in an office, you know, with local anesthesia.
So the idea was good, but I never could -- my -- my -- my problem with the mini sling was there was not any objective way to control the tensioning. So you didn't know how loose to make it or how snug to make it, and that was a problem for me, so -- and I was happy with the conventional products anyway.
Q. Oh, you mentioned in your report evidence-based medicine that you -- I guess you try and follow evidence-based medicine?
A. To a big degree, yeah.
Q. What does that mean? What's evidence-based medicine?
A. Well, it's sort of like, you know, what -- what kind of study or what kind of -- needs to be done or what -- what is necessary. And there's different levels. What -- what seems to be the best in terms of trying to prove something causes something else to happen. So, for instance, an anecdotal report on something is not very

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power in terms of influencing a causal relationship compared to, say, a randomized controlled study, which is -- you know, as you know, randomized controlled studies are more of the standard by which a lot of these things are done. You know, a lot of these decisions are made about what works and what doesn't work and what's the complications and what -- and . . .
So, you know, that and in conjunction with my experience, you know, and my own personal things going -- you know, in my practice are the things that influence me the most.
Q. What is a monograph?
A. Monograph, it's like a report. Sometimes it's a report written by somebody that has a -- they have an opinion about it, about some -- some issue or some --
Q. You mention in your report the 2007 Prolift surgeon monograph?
A. 2007?
Q. Yeah.
A. I'd have to see it.
MS. DEMING: Is there a question pending?
Q. (BY MR. MONSOUR) Yeah, why did you mention the 2007 Prolift surgeon monograph?
A. Well, I'd have to -- I'd have to look and see.

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MS. DEMING: Where are you reading?
Q. (BY MR. MONSOUR) It's on page 36 of your report at the bottom.
MS. DEMING: On the Prolift or TVT or -- yeah, Prolift, I presume.
MR. MONSOUR: I presume it would be Prolift.
MS. DEMING: Yeah, what page?
MR. MONSOUR: Page 36 at the bottom. It's near the end of the report.
MS. DEMING: Here it is. That's what he's talking about.
Q. (BY MR. MONSOUR) And I'll read it to you. It's -- just so the record's clear. On page 36 of your Prolift report, it says, "The professional education materials in 2007 Prolift surgeon monograph which supplement the IFUs warn of complications like contraction, erosion, pain, and dyspareunia and discuss management of these complications."
Did I read that correctly?
A. Yes.
Q. And so why did you mention --
THE WITNESS: Did we put in --
MS. DEMING: No, that's not -- we didn't put that in the -- I mean, we didn't -- these were articles,

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so . . .
Q. (BY MR. MONSOUR) So why did you refer to the monograph?
A. The -- it must have come as an additional paper.
Q. So tell me --
A. It could have been -- and I think it was -- I have to look at some of the materials that I had. We had brochures and a variety of things. I'd have to pull that out and see exactly. But it would talk -- it -- I'm sure without -- I'd have to look at it to see exactly how it was worded, but, you know, whenever you saw the certain types of complications that discussed, you know, certain ways to manage them.
Q. Where does the monograph come in to the surgeon's process? Where do y'all use the monographs at?
A. Well, if the -- if, for instance, you had a patient who had an erosion or who had some -- or pain and -- then it would discuss, you know, how to manage that with regard to what -- what -- what other options there were, what other conditions there were that may have caused the problem. And then if it was a surgical problem, how the -- what technique would be used.
Q. How do you get the monograph? Does the company send them to you?

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A. The company provided that.
Q. And is that -- is -- is the monograph -- is it something you keep in your office or --
A. It could have been. I mean, it could have been -- there were a lot of materials related to Prolift and the -- and the instructions on how to place Prolift and that kind of thing and how to place the trocars, et cetera, and all that. And then they would -- then they would -- there may have been -- after the initial Prolift launch, then they may -- as issues that came up that might have been related to the Prolift, then they may have come up with a monograph that came from the company. Do you need to --
Q. How is an instruction for use different than a monograph?
A. It may have been a supplement to the -- in other words, instead of reproducing another IFU, it might have been an addition to the IFU.
Q. Do you know or are you guessing?
A. I'm -- I'm not 100 percent sure, but I need to have that in front of me and then I could tell you.
Q. Okay.
MR. MONSOUR: Did you say it was attached?
MS. DEMING: No, it's not. We don't --

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MR. MONSOUR: It's in there?
MS. DEMING: No, it is not.
MS. KROTTINGER: Is it on the thumb drive of reliance materials?
MS. DEMING: Yeah, absolutely, but I don't think we brought one here that we can get it.
THE WITNESS: I thought I had some patient brochures -- maybe they're with those -- maybe they're with the case-specific.
MS. DEMING: Let me -- let me look. Let me look.
Q. (BY MR. MONSOUR) My -- I won't go into it too much. I'm just more generally asking questions.
Is -- when you would -- I know you did preceptor work for Ethicon. But did you also -- when they would have meetings and have, like, a lecture portion and then the cadaver lab following, would you ever be one of the lecturers?
A. Typically -- I may have been a lecturer on a couple of occasions. I was a lecturer with Prosima. But Prolift, I don't think so. I think I was just a -- it may have been a -- and with slings, I was more of a -- a proctor in the cadaver lab.
Q. Okay.

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MS. DEMING: And, by the way, I did receive the one for you, if you want it --
MR. MONSOUR: Okay.
MS. DEMING: -- that has the --
MR. MONSOUR: Hand it to her.
MS. DEMING: It's now yours. And I think when you try to open it, it will tell -- you should know what the plaintiffs' password is. I don't. I mean, they didn't tell me what it was, but it's what they do for everybody.
MR. MONSOUR: Okay.
MS. DEMING: Whatever that is. I can -- if you have a problem, call me.
MS. KROTTINGER: Okay.
Q. (BY MR. MONSOUR) When you go through either a surgery with one of your patients and you're explaining what the surgery is, you typically talk about the risks and the benefits, I would assume?
A. I do.
Q. One of the things that I've seen in this litigation is various pamphlets that Ethicon's made with regard to either the TVT or to the Prolift.
A. Yes.
Q. Have you ever seen any of those?

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A. Oh, yes.
Q. Did -- did you ever use those in your practice and -- to kind of help explain things --
A. Yes.
Q. -- or maybe give them to the patients when they were leaving?
A. Yes.
Q. What is the purpose of those handouts?
A. Well, they're typically written on maybe a -- you know, on a level that most people can understand, because trying to go through pelvic anatomy with a patient is not easy.
Q. Right.
A. And so the diagrams that were in were very simple, so it was very useful from that perspective. And -- so -- so it was a -- it was a -- it was a really nice educational tool. I could say, you know, we're going to be doing this repair and we're going to be using this product and this is the way it looks and this is the way it looks when we put it in your body and this is what it's designed to do.
Q. But the intention of those products is to, I guess, provide the patient with a more understandable version of the procedure and/or the product?

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MS. DEMING: Object to the form.
A. Well, yeah. And the way I -- I never did just hand the -- say, listen, this is what we're going to do and go home.
Q. (BY MR. MONSOUR) I didn't figure you would.
A. Because that was -- that was useless. And I think I -- I don't think -- I didn't have the Ethicon brochure on my wall, but if you came to my office and you went in my exam rooms, I have diagrams all over the walls, so depending on what I needed to reference for patients and -- where the pictures were big. So I use that, a lot of -- I'm a very visual person and I -- it's a lot easier to explain things in picture form than it is to try to explain it in any other way. So that was my main way of using it.
And then I would -- then I would -- after explaining it on there and maybe jotting a note or something, then I would hand it to the patient so they could keep that and refer to it. And then oftentimes they would come back for their preop visit with questions related to the surgery that they -- that they -- that the question was derived from what -- when they read those brochures.
Q. Okay. We've been going about an hour. Let's

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take a break.
(Short recess.)
Q. (BY MR. MONSOUR) Let's go back on the record.
We've had a short break. Are you ready to continue?
A. Yes, uh-huh.
Q. A couple of things. I just need to do some housekeeping. With regard to your qualifications, you are not a -- a pathologist, correct?
A. I'm not a pathologist.
Q. You are not a polymer science expert, correct?
A. I -- from what perspective?
Q. As far as how polymers perform, are made, degrade, those types of things. You are not a polymer science expert?
A. I'm not a polymer scientist.
Q. Okay. All right. You are -- you are not an FDA expert, correct?
A. I mean, in what -- I mean, how -- I don't know what you mean by "expert." How do you become an FDA expert?
Q. Well, if you were one, you would probably know. So --
A. Look -- look, how the -- how the FDA may -- and

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its -- and its regulation about these products and how I used them, yeah, I have some knowledge about that. And how the FDA classifies devices, I have some knowledge about that. So, I mean, from -- I don't know what the definition of an "expert" is, but --
Q. Let me ask it this way. I have some knowledge about automobiles, but you wouldn't want me fixing your car. I own a car. I own several cars. I've owned many over the years. I'm not a car expert at all. And that's kind of what I'm getting at.
I mean, it -- your expertise is limited to gynecology. Is that a fair statement?
MS. DEMING: Object to the form.
A. Well, yes. And anything that applies to gynecology that might be somewhere -- I mean -- I mean -- go ahead.
Q. (BY MR. MONSOUR) But I'm trying to short-circuit this. Your expertise is limited to gynecology and clinical aspects of gynecology. Is that a fair statement?
MS. DEMING: Object to the form.
A. I wouldn't say it's limited to, but it certainly is inclusive of anything that has to do with gynecologic surgery and anything that's affecting gynecologic surgery, then I feel I have pretty good expertise about.

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Q. (BY MR. MONSOUR) Okay.
MS. DEMING: I can assure you he is not going to be offered as an expert to talk about 510(k) process and how it goes through the regulations for FDA requirements. In that respect, he is not a regulatory expert. If that helps you at all. Nor is he going to be offered to take a regulation of the FDA and -- and talk to the jury about it, nor do I understand whether Judge Goodwin will even allow it.
MR. MONSOUR: These questions weren't my idea.
MS. DEMING: I understand. I know exactly.
MR. MONSOUR: It's my two compadres here.
MS. DEMING: It's not the first.
MS. KROTTINGER: It's an expert deposition. We want to know what he's an expert in.
MS. DEMING: And you are entitled to. I'm just trying to shortcut it to --
Q. (BY MR. MONSOUR) So I'm -- I'm going to ask it another broad way. Other than gynecology -- other than gynecology, what are you an expert in?
A. Fly fishing.
Q. Okay. Okay.
A. How's that?

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Q. All right. Okay.
MS. DEMING: Are we through?
MS. KROTTINGER: Could you introduce these as exhibits?
MR. MONSOUR: Let me mark this as Exhibit 6.
(Exhibit 6 marked.)
Q. (BY MR. MONSOUR) Exhibit 6, Dr. Shoemaker, is your TVT midurethral sling expert report, correct?
A. Yes.
(Exhibit 7 marked.)
Q. (BY MR. MONSOUR) And Exhibit No. 7 is your Prolift pelvic organ prolapse expert report, correct?
A. Yes.
Q. Anything in either one of those two expert reports that you need to supplement or change, as we sit here today?
A. No.
MS. DEMING: I just have a couple of questions.
MR. MONSOUR: Okay. Nothing -- I'll pass the witness.
EXAMINATION
BY MS. DEMING:
Q. With respect to Exhibits 6 and 7, do these

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incorporate the opinions that you've formed in connection with this case --
A. Yes.
Q. Okay.
-- with this -- the general aspects of this pelvic mesh litigation?
A. Yes.
Q. He asked you some questions about the brochure and how you use the patient brochure. Do you --
A. Yes.
Q. -- remember those questions?
A. Yes.
Q. In -- in the way that you use the brochure, is it -- do you -- in -- strike that.
Is the brochure ever intended to supplant your discussions with the patients?
A. No.
Q. How is it to be used?
A. No. I use it in conjunction with my discussion with the patient about what the surgery's going to be and mainly use it to -- to demonstrate schematically, you know, what the operation's going to entail and what products would I be using to help supplant it, her implant.

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Q. Mr. Monsour asked you some questions about the IFU and the bases of your expertise in connection with the IFU. What, if any, role does the teaching or the preceptorships that you have participated in in -- with respect to the pelvic mesh, what, if any, role does that have or inform you about with -- insofar as your expertise as a labeling person is?
A. You mean how have I used the IFU in terms of teaching another doctor?
Q. No, what I'm asking about that -- when you test -- or, rather, when you have given an opinion in your report --
A. Right.
Q. -- about the adequacy of the IFU for one of these mesh products, does your role in teaching and your discussions with the physicians that you teach inform that expertise?
A. Inform the expertise?
Q. Yes.
A. Yes.
Q. Does your assistance at meetings -- you mentioned one, but the professional meetings and whatnot where you have these discussions with doctors, does that inform your expertise?

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A. Oh, absolutely, yes.
Q. That's all I have.
MR. MONSOUR: I have nothing further.
MS. DEMING: I thank you.
(Deposition concluded.)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

_____ JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

Jane Doe
Case No. 2:12-cv-00000

REPORTER'S CERTIFICATION
DEPOSITION OF STANTON SHOEMAKER, M.D.
TAKEN APRIL 5, 2016

I, RENE WHITE MOAREFI, Certified Shorthand Reporter and Notary Public in and for the State of Texas, hereby certify to the following:

That the witness, STANTON SHOEMAKER, M.D., was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to DOUGLAS C. MONSOUR, ESQ.;

That a copy of this certificate was served on all parties and/or the witness shown herein on

_____.

I further certify that pursuant to FRCP No. 30(f)(i) that the signature of the deponent was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties in the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Certified to by me this 15th day of April, 2016.

_____
RENE WHITE MOAREFI, CSR, CRR, RPR
My notary commission expires 10-28-18

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